Exhibit C

IN THE CIRCUIT COURT OF JASPER COUNTY, MISSOURI
AT JOPLIN

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CONNIE SCHUBERT and KEVIN SCHUBERT, Plaintiffs,	:	
v.	:	Case No. 10-A0-CC00219
CHRISTOPHER H. ROBERTS, M.D., FREEMAN HEALTH SYSTEM d/b/a SOUTHWEST WOMEN'S CENTER, FREEMAN HEALTH SYSTEMS, ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, and JOHNSON & JOHNSON, Defendants.	:	

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August 12, 2013

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Videotaped expert deposition of TIMOTHY A. ULATOWSKI, taken pursuant to notice, was held at the law offices of O'Melveny & Myers LLP, 1625 Eye St, NW, Washington, DC, commencing at 10:39 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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VIDEOTAPE TECHNICIAN:
Michael Gay

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I N D E X

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DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer

Request for Production of Documents

Stipulations

Question Marked

- - -

(Deposition Exhibit No. Ulatowski-1, 8/5/13 E-Mail from Slater to Kabbash Enclosing Notice to Take Videotaped Deposition Duces Tecum of Timothy A. Ulatowski, was marked for identification.)

- - -

(Deposition Exhibit No. Ulatowski-2, Defendants Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare & Johnson & Johnson's Disclosure of Expert Testimony, was marked for identification.)

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(Deposition Exhibit No. Ulatowski-3, (Exhibit 3) Curriculum Vitae of Timothy A. Ulatowski, was marked for identification.)

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(Deposition Exhibit No. Ulatowski-4, (Appendix A) Curriculum Vitae for Timothy A. Ulatowski, was marked for identification.)

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(Deposition Exhibit No. Ulatowski-5, Ethicon Expert Report of Timothy A. Ulatowski, M.S., In re: Pelvic

Mesh/Gynecare Litigation, Case No. 291 CT, Master Case 6341-10, was marked for identification.)

- - -

(Deposition Exhibit No. Ulatowski-6, Supplemental Ethicon Expert Report of Timothy A. Ulatowski, M.S., In re: Pelvic Mesh/Gynecare Litigation, Case No. 291 CT, Master Case 6341-10, was marked for identification.)

- - -

(Deposition Exhibit No. Ulatowski-7, "Appendix B, Materials Reviewed and Public Sources of References", was marked for identification.)

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(Deposition Exhibit No. Ulatowski-8, 4/1/11 Letter from Gage to Ulatowski, was marked for identification.)

- - -

(Deposition Exhibit No. Ulatowski-9, Two-Page Document Labeled "Prior Testimony", was marked for identification.)

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(Deposition Exhibit No. Ulatowski-10, Various Invoices from Ulatowski to Butler Snow, were marked for identification.)

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THE VIDEO TECHNICIAN: We are on the record. The time now is 10:35. This marks the beginning of disc number one for the videotape deposition testimony of Timothy A. Utalowski in the matter of Schubert versus Ethicon, et al.

This case is pending in the Circuit Court of Jasper County, Missouri at Joplin, Case No. 10AO-CC00219.

Today's date is August the 12th, 2013. This deposition is being conducted at 1625 Eye Street, Northwest, Washington, D.C.

Will all attorneys present please identify themselves and who they represent?

MR. SLATER: Adam Slater on behalf of the plaintiffs.

MR. DONELAN: Andrew Donelan on behalf of Freeman Health System.

MS. MINKIN: Susan Minkin on behalf of plaintiffs, but here merely for taking care of the exhibits and so on.

MS. KABBASH: Maha Kabbash from Riker

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Danzig on behalf of Defendants J & J and Ethicon.
THE VIDEO TECHNICIAN: My name is Michael Gay. I'm with Golkow Technologies. Our court reporter today is Kim Cahill, also with Golkow Technologies, and we'll now swear in our witness.
- - -
TIMOTHY A. ULATOWSKI, after having been duly sworn, was examined and testified as follows:
- - -
THE VIDEO TECHNICIAN: You may proceed.
- - -
EXAMINATION
- - -
BY MR. SLATER:
Q. Good morning, Mr. Utalowski.
A. Morning. Can I tell you that there's some background talking or whatever that probably should be reduced, if possible, either your location or --
Q. I don't know what you're talking -- certainly not from my location. I'm the only person speaking in here.
A. Perhaps --

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Q. If there's someone in a different location, maybe they can -- let me speak. Maybe if anyone is in a different location on this conference, they can mute their mic, please, unless they need to object or something. It will probably make it a cleaner sound.
Is that better?
MS. MINKIN: I don't have a mic.
MR. SLATER: Are you still hearing the sound, sir? Did that solve our problem?
THE WITNESS: I think that did it.
MS. KABBASH: Actually, it sounds like it did.
THE WITNESS: Yeah.
MS. KABBASH: Yeah.
THE WITNESS: Yes.
MR. SLATER: Okay. Terrific.
BY MR. SLATER:
Q. Okay, Mr. Utalowski. I'm here to take your deposition in this lawsuit. You understand that. Right?
A. Yes.
Q. You understand you must tell the truth in response to each one of my questions. Right?

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A. Yes.
Q. If my question is unclear to you for some reason, please explain to me what's unclear and we'll clarify what the question is. Okay?
A. Okay.
Q. Now, I've marked as Exhibit 1 the deposition notice. Did you see this deposition notice --
A. Yes.
Q. -- before now?
A. Yes.
Q. Did you -- did you bring the documents that were requested to be produced?
A. I brought --
Q. Or at least identify them -- or at least identify them on the disclosures?
A. I brought what Ms. Kabbash didn't have in her possession, so, yes, I think all the documents are there.
Q. What did you bring with you?
A. I brought invoices. I brought the deposition testimony PDF. I think that's about it; otherwise, she had my C.V., whatever else.
Q. When you say you brought the deposition testimony, what deposition testimony are

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you referring to?
A. Well, that's a two-page PDF of my prior testimony.
Q. You're talking about the list. You didn't bring the actual transcripts.
A. No, no, no, just the list.
Q. Okay. We'll come back to that.
Exhibit 2 is the disclosures that were made by Ethicon and Johnson & Johnson and on page 3 are disclosures with regard to you. Please turn to page 3.
A. (Witness complies.) Okay.
Q. Have you seen this document?
A. Yes.
Q. Did you see the document before it was served?
A. "Before it was served."
Q. Sure. There's a stamp on the front, sir, that says July 15th, 2013. Did you see it before that date?
A. I don't think so.
Q. The content of point number 3 in this document that spans pages 3 and 4, had you seen that content before July 15th, 2013?
A. In this specific document?

Q. Whether in this document or in another form.
A. Well, I've seen similar language in prior disclosures.
Q. Did you see this language at any point before July 15, 2013?
A. I don't recall. I may have received an e-mail with this disclosure and I looked at it. I just don't recall.
Q. So as you sit here now, you don't recall seeing the language that's set forth in item number 3 regarding your testimony before July 15th, 2013; correct?
A. Not that I can recall.
Q. When do you recall first seeing this document?
A. Well, as I said, I think I received an e-mail with it and I looked at it, but I certainly also saw it this morning.
Q. When you received the e-mail, when was that?
A. I don't recall. I'd have to check my records.
Q. Now, Exhibit 3, it's my understanding, is your up-to-date C.V.; is that

correct?
A. Yes.
Q. You have a section on the first page of your C.V. titled "Selection of Notable Accomplishments," and it talks about you being a regulatory expert in litigation for either defendant or plaintiff.
Do you see that?
A. Yes.
Q. Have you been an expert for a plaintiff in litigation?
A. Yes.
Q. When?
A. Well, we can go through my PDF of the prior testimony, for example.
Q. Fine. That's Exhibit 9; correct?
A. You tell me.
MS. KABBASH: Let's see.
MR. SLATER: It's marked as Exhibit 9.
MS. KABBASH: Yes, it is.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Exhibit 9 is a list of all the deposition testimony you've given and the court

testimony you've given; correct?
A. Correct.
Q. Tell me, in the depositions, which were on behalf of the plaintiff.
A. Okay. I will do that.
Number 1, number 11. That's on deposition testimony, there are two. And none on court testimony.
Q. So you've been an expert for a plaintiff on two occasions; correct?
A. Yes, so far in deposition testimony, yes.
Q. The first -- well, in cases -- in all cases, how many times have you been an expert for the plaintiff?
A. Well, there's -- I haven't provided deposition testimony in -- in one additional case.
Q. What case is that?
A. That's similar to number 11, but it's a different plaintiff. The plaintiff in that case is Center City Periodontists versus Dentsply International.
Q. What's the subject matter of those lawsuits that you're opining on? What's the issue?
A. Well, number 1 was concerning --

Q. Let me -- let me stop you. Time-out, sir. Let me stop you, because my question wasn't clear. I want to make sure it's very clear.
What is the subject matter of the litigation listed as number 1 on your prior testimony?
A. Okay. Number 1, oh, it had aspects of contracts, 510(k) changes, whether or not a 510(k) submission was required, labeling issues. So that's -- that's basically number 1.
Q. Was it with regard -- well, rephrase.
What was the device or drug that's at issue in the litigation listed in number 1 that starts "University of Pittsburgh"?
A. It's a medical device, first of all. Secondly --
Q. What type?
A. That's what I was going to just tell you -- number 2, it was a diagnostic device, a device used in radiology.
Q. Number 2?
A. Oh, number 2 --
Q. Did you say number 2?
A. I thought you -- I thought you said number 1.

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Q. I'm not asking you about number 2. I'm only asking you about number 1.
A. That's what I'm saying.
Q. Number 1, it was a medical -- let me finish my question.
Number 1 relates to a medical device used for diagnostic radiology?
A. That's correct.
Q. What's the name of the device?
A. I don't recall the trade name right now.
Q. And you're an expert for the plaintiff. Who's the plaintiff in that case?
A. It's Pittsburgh, U of Pittsburgh is one of the plaintiffs.
Q. And what is their claim in that case?
A. Well, I mentioned the element -- the regulatory elements that I testified to. Of course, the complaint had various aspects that were both regulatory and nonregulatory. One of the aspects that I opined on was regarding 510(k) submissions and labeling aspects.
Q. Did you have the opinion in that case that a device required a 510(k) and it wasn't obtained?

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A. I believe so, yes.
Q. Who retained you in that case? Who's the lawyers that retained you?
A. I don't recall right now.
Q. The item that's listed as number 11, Weinstat versus Dentsply International, you're the expert for the plaintiff in that case?
A. Yes. And number 1, I think, was Patton Boggs, but I may be wrong on number 1.
Okay. Now your question on the later one?
Q. Yeah, now on number 11, you're the expert for the plaintiff in the Weinstat case?
A. Yes.
Q. What's the issue in that case?
A. Well, it was primarily labeling regarding 510(k)s submitted by Dentsply, specifically regarding infection control issues.
Q. Did you opine that there were deficiencies in the 510(k) submission?
A. I opined that there were deficiencies in the labeling for the product in terms of infection control practices.
Q. Infection control practices with the device at issue?

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A. Yes.
Q. And what's the device?
A. Ultrasonic scalers.
Q. And then there's a second case for a different plaintiff, but the same issue, against the same defendant, in which you're the expert as well?
A. Well, somewhat the same issue. There's -- there's primarily two elements in the Weinstat case, and there's only one of the elements in the Center City case.
Q. The plaintiff is Center City in that case?
A. Yes, Center City Periodontists is the -- is the name of the plaintiffs.
Q. Okay.
In your time at the FDA, did you ever oversee any issues with regard to a pelvic mesh device or product?
A. In my capacity as Director of Compliance, generally I had oversight on all medical devices in regard to enforcement and compliance.
Q. Did you ever have any direct oversight of a labeling issue with regard to a pelvic mesh device where you actually had involvement?

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A. None that comes to mind.
Q. Did you ever have direct involvement with any 510(k) issue with regard to any pelvic mesh device while you were at the FDA?
A. None that comes to mind.
Q. Did you ever have any direct involvement with any labeling or 510(k) issue with regard to any hernia mesh product or device when you were with the FDA?
A. Not that I can recall.
Q. Did you have any direct involvement with the labeling or 510(k) or any other issue when you were at the FDA with regard to any surgical mesh product or device?
A. Not that I can recall, but let me just add that one of my responsibilities was overseeing the recall program, so if there were any recalls, for example, that would have been generally under the purview of my office.
But I don't recollect any specific actions or activities related to mesh.
Q. As you sit here now, you don't recall any instance in which you had any direct involvement with labeling, 510(k), or any other issue with regard to any surgical mesh device or product;

correct?
A. I don't recall any specific activity, action, or otherwise specifically on those items.
Q. You have in front of you Exhibits 4 and 5, which are reports that you authored and served in a different litigation in the State of New Jersey.
Do you have those in front of you?
A. Yes, I do.
Q. Do you have any additional opinions in this case other than those that are set forth in those reports?
A. Well, I guess that would depend upon any positions plaintiff may bring forward. Of course, my -- the exhibit we've already gone over in terms of the disclosure outlines the scope of my testimony.
Q. Well, let me explain to you what I'm driving at here. A disclosure is a broadly worded document that lawyers write to try to generally encompass almost everything under the sun, so my opportunity today is to find out what opinions you've actually formed and to talk directly to you, rather than just taking a lawyer's word for it.
So with that preface, let me now get

to the question I want to ask you: In your reports that are marked as Exhibits 4 and 5, you set forth certain specific opinions you had reached; correct?
A. At that point in time, yes.
Q. And as you sit here right now, have you reached additional opinions that are not set forth in those reports that you intend to give in this trial of this case?
A. Well, I can't foresee what issues may be brought up during trial testimony or whatever, but -- that would elicit an opinion, so with that caveat -- that's the only caveat I have.
Q. As you sit here now, you have no additional opinions beyond those opinions set forth in Exhibits 4 and 5; correct?
A. As I sit here right now, yes.
Q. You were deposed in the New Jersey litigation for two days; correct?
A. Yes.
Q. Did you read those deposition transcripts?
A. Yes.
Q. As you sit here now, is there anything that you testified to in those depositions of those two days that you would correct if you

could right now or do you stand behind all that testimony?
A. I --
MS. KABBASH: Objection.
You can answer.
THE WITNESS: I didn't see any issue with what I stated in the deposition testimony.
BY MR. SLATER:
Q. Exhibit 6 is the list of materials you had reviewed in connection with the report that you wrote that's marked as Exhibit 4 and I believe potentially Exhibit 5 as well.
Those where the materials you had reviewed at that point in time and when you were deposed in that New Jersey litigation; correct?
A. Yes.
Q. There's -- now -- rephrase.
Exhibit 7 is what we were given today, which I was told is an updated list of materials that you have reviewed in connection with this litigation; correct?
A. Not entirely in regard to this litigation, but these are additional materials I've been provided in regard generally to the issue of mesh.

Q. The materials that are on Exhibit 7 obviously are -- well, rephrase.
To the extent that there are materials listed in Exhibit 7, which is your updated list of materials reviewed -- rephrase.
To the extent there are additional materials listed on Exhibit 7, your updated list of what you reviewed, as compared to your prior list, those new materials that you've reviewed -- I'm calling them new because you hadn't reviewed them when you wrote your first report -- has not altered or expanded or changed your opinions in this litigation; correct?
A. I don't believe so. I think primarily the additional materials concern TVT since the last deposition testimony. There's a couple additional mesh documents, but -- but generally I don't -- I don't think the additional documents change my opinions in regard to my prior report or add to.
Q. As you sit here now -- I'm sorry. I didn't mean to interrupt you.
A. I said or add to.
Q. Okay. There's a little delay, so we may talk over each other once in a while. I'm sure

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it will be unintentional.
So to the extent additional materials are listed on Exhibit 7 as compared to Exhibit 6, the review of those materials did not change the opinions that you hold in this litigation; correct?
A. That's correct.
Q. There's a list of deposition transcripts on -- and we'll go from Exhibit 7 at this point because that's your updated list.
Did you read each one of those deposition transcripts completely?
A. Yes, uh-hum. Yes.
Q. And did you read all of the exhibits that were -- that were provided with each of the transcripts?
A. Yes, I -- I coursed through them as I -- after I reviewed the depositions. Now, not all depositions necessarily had exhibits attached to them. I think most of them had, but -- but, yes, I do course through the exhibits.
Q. When you say you course through the exhibits, does that mean that you skim through them, but you don't read them all in their entirety?
A. Well, it may be an exhibit I've seen before in a prior deposition. It may be not

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specifically related to a regulatory matter, so it varies depending on the exhibit.
Q. To the extent that you were provided exhibits for the various depositions as set forth in Exhibit 7, is it fair to say you did not read every single one of those exhibits in their entirety?
A. Well, I'm a quick reader, so I look through them to determine their content, relevance, whether I've seen them before, as I just mentioned. So have I read them through, yes --
Q. Sir -- sir, I'm going to interrupt you now, because I didn't ask you -- and with all due respect, I didn't ask you if you're a quick reader and I didn't ask you anything else other than one specific pointed question, so I'm going to ask the question again and ask you for a direct answer.
Am I correct that with regard to the exhibits for the deposition transcripts listed here on Exhibit 7, you did not read each and every exhibit in its entirety?
A. And the answer is no if it was a duplicate of -- if it was the same document in a prior deposition or something else I've seen already.
Q. With that caveat, with that

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exception, you're saying you read every document that was an exhibit to a deposition that was provided to you.
A. Yes.
Q. And if I wanted to know what exhibits those were that were provided to you, are they listed within this list of materials reviewed separately?
A. I don't think so necessarily. We'd have to look at this. It just says exhibits.
Q. You understand what I'm getting at?
A. No. If you could be more clear.
Q. Here's what I want to know -- well, here's what I want to know: If I wanted to know what exhibits you saw, for example, Jennifer Paine's deposition transcript, how would I find that out?
A. Well, I'm sure Ms. Kabbash could provide additional listing or I could construct one given time.
Q. Well, here's what I want to know, because if you were provided exhibits from deposition transcripts, you don't know if it was all the exhibits or not. You just know, these are exhibits I was provided; correct?
A. That's correct. And I think in one

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or two situations, based on the numbering of the exhibits, there appeared to be missing exhibits that were, in a couple cases, subsequently provided, so -- that's my answer.
Q. Okay.
As you sit here now, you don't know if you were provided every exhibit from every one of the depositions listed here; correct?
MS. KABBASH: Objection.
THE WITNESS: I can't attest to that right now.
MR. SLATER: You just don't know.
THE WITNESS: I don't know right now.
MR. SLATER: Okay.
BY MR. SLATER:
Q. And if I wanted to know what exhibits you reviewed from each of the depositions, for example, the first one listed, Jennifer Paine, would you be able to tell me that as you sit here now?
A. Oh, no. It was a long list. No, I couldn't tell you offhand.
Q. Let's look a little further down on the list of transcripts. There's David Robinson. It says, "deposition transcript with exhibits."
Do you see that?

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A. Hang on just a moment. Where are you? First page?
Q. First page of Exhibit 7.
A. Okay.
Q. Yep. It says deposition transcripts -- well, it says "transcript," actually, and it says David Robinson --
A. Yes.
Q. -- "deposition transcript with exhibits."
Do you see that?
A. Yes.
Q. What day deposition transcript of David Robinson were you provided and did you read as listed here?
A. Well, I think I'd probably turn to my report, where I do list dates of the deposition testimony. So, for example, that's what I would do to try and correlate what's stated here to the exact date.
Q. When you say that the dates of the deposition testimony are listed, do you mean when you make a direct citation to testimony and you said in the citation that you're citing to the -- whatever date it was, transcript of a certain

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witness?
A. That's my style to indicate the date of the --
Q. Okay.
A. -- deposition testimony.
Q. Beyond what's actually cited in your report, are you able to tell me what specific date or dates of deposition transcripts you were provided for each of these witnesses?
A. Not without looking at my report.
Q. Well, let's, for example, take David Robinson. From looking at your report, would you be able to tell me what date or dates of deposition transcripts you were provided from his deposition?
A. I believe so. If you want me to do that, I can do that right now.
Q. Well, we're going to make a note and later on, I'll -- well, actually, let me ask you, how would you do it? You would just flip through the report and have to read every page and look for his name and see what you cited?
A. That would be basically what I would do.
Q. So if I were to read your report, if I want to know what dates of deposition transcripts

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you reviewed, I would just look to see what is cited in the report and that tells me what you saw; correct?
A. I believe that's the case.
Q. Okay.
Why did you cite to -- well, rephrase.
You looked at various documents regarding the TVT devices; correct?
A. Yes.
Q. Are those of significance to you in forming your opinions in this case?
A. In this particular case, somewhat related, but not specifically in regard to pelvic mesh, but I was provided those documents generally as a -- as an expert.
And, of course, TVT is still unfolding as far as cases that may present, so I have those documents. They were listed as reliance documents and it is what it is.
Q. In this trial, which is going to involve the Prolift and Prolift+M, you would not expect that you would be referring to or relying on TVT documents; correct?
A. Well, I can't say with certainty

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regarding that, because there's some -- there's some relevance -- regulatory relevance here and there, so I guess it depends.
Q. Well, tell me right now what TVT document you would be relying on at the trial of this case with regard to the Prolift and Prolift+M and how you would rely on it.
A. Okay. I'll give you an example that just comes to mind. I think in evaluating TVT-Secur, as I recall -- I'm still looking at documents, but -- Dr. Herrara at FDA who had been evaluating the 510(k) for that product was commenting on the bidirectional elasticity claim that he saw in TVT and, at that point in time, made a comment, but did not appear to explore it further, noting that it had been in labeling, noting the claim, and then not asking Ethicon to delete the claim.
So -- and then the claim comes up later on in Prolift and Prolift+M, and this is already what FDA's seen, this claim, in a prior submission.
Q. Well, with regard to the bidirectional elasticity claim, you're talking about the claim that was found in the Prolift IFU

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originally that said the bidirectional elasticity of the Prolift allows adaptation to the stresses or physiologic stresses in the body; correct?
A. Yes.
Q. And you know that Ethicon eventually had to admit to the FDA they did not have data to support that statement and removed it from the IFU as a result; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, as you've characterized it, I'm not quite sure that's the case. I think they certainly deleted the claim, but whether they, in quotes, out of quotes, admitted to not having the data, I think they acquiesced to FDA's request.
BY MR. SLATER:
Q. Well, you know that the FDA told Ethicon that unless they could provide data to support the claim, they needed to remove the statement. And Ethicon went back to the FDA and said, we don't have data to support the statement and we're removing the claim.
That is what factually occurred; correct?
MS. KABBASH: Objection.

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THE WITNESS: Well, we'd have to -- we'd have to refer to documents. I -- I know that Ethicon acquiesced to the request. Whether or not they had data or not, I think there's some testimony that goes beyond what you've stated, but that's my understanding in terms of their acquiescence to the request.
BY MR. SLATER:
Q. As you sit here right now, do you know whether or not Ethicon was able to produce data to support the bidirectional elasticity claim to the FDA?
A. I don't believe in the final step before removing the claim Ethicon chose to provide data to support the claim. Whether or not they had data, I think I've seen some conflicting testimony regarding that, but they did not supply that information and pursue the claim.
Q. When the FDA asked Ethicon to produce data to support the bidirectional elasticity claim, Ethicon was unable to produce such data to the FDA; correct?
A. Well, I -- I'm -- I'm recollecting deposition testimony that internal discussions about that and information that -- that Ethicon had, in

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the final result, they decided not to pursue the claim and deleted it.
Q. Well, in the documents you've seen, have you ever seen a document where people within Ethicon during the back-and-forth with the FDA in 2000 and 2008 internally said they did have data to support the bidirectional elasticity claim? Is that your testimony?
A. I'm just recollecting deposition testimony in regard to that. I think that --
Q. Whose testimony?
A. I don't recall offhand right now, but --
Q. Are you -- are you testifying that there's a witness who testified in their deposition that Ethicon had data to support the bidirectional elasticity claim and chose not to give that data to the FDA? Is that your testimony?
A. Well --
MS. KABBASH: Objection.
THE WITNESS: Excuse me. I think that they had a -- they had an explanation for the claim. They had data -- they had information to respond, an explanation. They chose not to pursue the claim and deleted the claim.

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BY MR. SLATER:
Q. Why are you talking about explanations, with all due respect? It's a very direct question that you fully understand, so I'm going to ask it one last time.
Is it your testimony that you saw documents or deposition testimony indicating that Ethicon internally had data to support the bidirectional elasticity claim and chose not to give it to the FDA? Is that your testimony?
MS. KABBASH: Objection.
THE WITNESS: I can't recall with certainty --
MR. SLATER: It's a simple yes or no question.
THE WITNESS: And I was just in the process of answering you and I -- I'm recollecting deposition testimony. Whether -- I don't recall seeing a report or a test necessarily, but I just recall generally the deposition testimony and the -- and how this all ended up.
And I recall that, in looking at the TVT data, that FDA had seen the claim before.
MR. SLATER: Okay.
I'm going to move to strike the

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answer.
BY MR. SLATER:
Q. Is the answer to my question that I just asked you a moment ago "yes" or is the answer "no"?
MS. KABBASH: Objection.
THE WITNESS: I'm not sure I can answer "yes" or "no," because I -- I just don't recollect the foundation for Ethicon's position; but as far as I do recall, they had been constructing a response in regard to that question.
I don't recall, sir, what the data set was, if there was any, to support the claim.
BY MR. SLATER:
Q. I'd like you to assume the following hypothetical facts: I'd like you to assume that during the time the Prolift IFU made the claim that the bidirectional elastic property allows adaptation to various stresses encountered in the body, during the time that was in the Prolift IFU, Ethicon did not have data to support that statement. I'd like you to assume that fact.
Okay?
A. Okay.
Q. If that is the fact, then the

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inclusion of that statement in the Prolift IFU would be misbranding; correct?
A. Well, I -- I would say -- I would go as far as saying it probably would be something to pull from the labeling. Whether it's misbranding or not, you know, that -- that determination requires some analysis.
Q. Did you ever perform that analysis up till this moment?
A. In regard to the specific claim?
Q. Yes.
A. No, I have not.
Q. You would agree with me that if my hypothetical is correct, that claim should not have been made in the Prolift IFU; correct?
A. I think the answer is yes. There has to be a foundation for the claim.
Q. You testified that you saw some documents regarding the TVT-Secur regarding a bidirectional elasticity claim regarding that device; correct?
A. As far as I recall, yes; but, again, I'm still coursing through TVT documents and evaluating a lot of information there.
Q. And I think what you testified to is

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that someone named Dr. Herrara at the FDA looked at the 510(k) submission for the TVT-Secur, saw that claim, made some sort of a comment on it, but did not ask to have that claim deleted or further explore that claim.
Do I understand that correctly?
A. Yes, that's correct.
Q. Did Ethicon -- well, rephrase.
Did that take place before or after -- well, rephrase.
That would have taken place before the 510(k) process for the Prolift and Prolift+M; correct? That would have been --
A. Yes.
Q. -- before that time period; correct?
A. Yes.
Q. If Ethicon knew that it -- rephrase. I'm going to ask you a hypothetical question: If Ethicon knew during the 510(k) process for the TVT-Secur that it did not have data to support a claim that the TVT-Secur device had a bidirectional elastic property and it was a claim they were going to make in their IFU, they needed to tell that affirmatively to the FDA so the FDA would know that during the process; correct?

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MS. KABBASH: Objection.
THE WITNESS: Interesting question. I think that they had the claim in the labeling. What was in the TVT-Secur 510(k) in the background there, I can't yet attest to because I'm still looking at documents, but, again, you have to have a foundation somewhere for a claim.
BY MR. SLATER:
Q. It's not acceptable for a medical device manufacturer like Ethicon to show its labeling to the FDA as part of a 510(k) process and to the extent the manufacturer knows that certain claims or statements made are not supported by any data, it's not acceptable to use those statements or include those statements; correct?
A. Well, I would say that -- that claims require a foundation, so anything stated in the labeling requires a foundation as far as statements made.
Q. Anything that is stated in any labeling for any medical device by a medical device manufacturer must have a foundation to support that statement; correct?
A. Yes, and that foundation can vary depending on what the claim is. It may be -- a

claim may be self-apparent on the -- because of the nature of the product, and I can describe a couple examples.

MR. SLATER: Move to strike after the word "yes."

BY MR. SLATER:

Q. The simple answer to my question is "yes"; correct?

MS. KABBASH: Objection.

THE WITNESS: Yes, there needs to be a foundation if -- I forget exactly your question, but, again, there needs to be a foundation.

BY MR. SLATER:

Q. With regard to the disclosure of risks in the IFU for the Prolift and Prolift+M, what is the standard for what risks need to be included? I don't want the specifics. We'll talk about specifics later, but what is the standard for what must be included?

A. Well, in terms -- the regulatory standard would be, first of all, from the statute in regard to adult -- misbranding; secondly, from the regulation in regard to labeling requirements for medical devices; and any guidance that may be helpful -- of course, guidance is not regulation.

That's not mandatory, but it may be helpful.

Q. In layman's terms, what is the standard that applied to the Prolift and Prolift+M IFUs in terms of what risks needed to be included in the IFUs? In layman's terms, how would you describe that simply to me?

A. Well, I would say that from the regulations, what the regulations call for is -- are in-prescription labeling, a description of intended -- of indications for use, precautions, contraindications, warnings, adverse effects. That's what's described in regulations.

So that's kind of the sum total of the regulatory description of what's required in labeling.

Q. Here's what I want to understand: If a regulatory professional at Ethicon is making a decision as to whether a risk needed to be included or not included in the IFU for the Prolift or Prolift+M, in simple terms, what should that regulatory professional have been trying to determine?

And I don't want you to just say he should have read the regs. I want to know, boiling it down, what is the question that that professional

had to answer in his or her own mind?

A. Well, I -- it depends on what professional you're talking about. In regard to --

Q. The -- I'll tell you who it is then, if you ask me that question.

I'm talking about the Ethicon Regulatory Affairs person whose job it was to decide whether or not the risks listed in the IFU was the proper list of risks, that person who had to make that decision.

A. Well, I think that the regulatory person at Ethicon would be following a procedure, first of all, in regard to developing --

Q. What is the question -- I want a very simple answer, sir. I'm not asking about the process. I'm asking a direct question: What is the question that person would need to answer in his or her own mind as to whether or not a risk needed to be included in the IFU?

A. Well, I was getting to there, sir, if you gave me -- give me about ten more seconds.

Q. Let's just get an answer to that, without background.

MS. KABBASH: Adam, I'm just going to ask you, and it may be because there's a video

delay, but sometimes you're clipping the beginning of his response.

So if you could just let a second pass to let him commence answering the question, just so that everything is a little cleaner. It might be that you don't realize that we have a bit of a delay.

MR. SLATER: Okay --

THE WITNESS: Well --

MR. SLATER: -- fair enough.

So can you give me a direct answer to that question, please?

THE WITNESS: The -- please repeat the question.

BY MR. SLATER:

Q. What is the question that the Regulatory Affairs person at Ethicon needed to answer in his or her own mind when deciding whether or not a risk needed to be disclosed in the Prolift or Prolift+M IFU?

A. It would be the questions posed in the procedure regarding construction of labeling.

Q. And with regard to a risk, of whether or not a risk needed to be included or not, in simple terms, what is the question that person was

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seeking to answer?
A. I believe that the regulatory personnel would be turning to the medical personnel in regard to development of several portions of the labeling in regard to adverse effects, warnings, for example, and that's probably how their procedure is laid out.
Q. And what would be the question that the Medical Affairs professional would be posing to Medical Affairs or seeking to answer through an interaction with Medical Affairs to determine what risks needed to be included in the Prolift or Prolift+M IFU?
A. Well, part of that incurs medical decision making and I'm not a clinician, so -- so any ingredients in regard to labeling would be subject to medical interpretation.
They would be asking questions on what are the risks, the probability, severity of the risks, the knowledge of the physician regarding those risks.
I'm sure there's a number of questions that probably would be posed.
Q. Well, as you sit here right now -- well, let me ask you this: With regard to whether

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or not the Prolift IFU adequately discloses the risks and adverse events with regard to the Prolift, from a regulatory perspective, am I accurate that you are -- you do not have an opinion on that subject because you do not have the medical background to answer that question?
A. From a -- from a medical position, what risks should be in there versus not in there, that's a medical -- in my mind, a medical analysis. What needs to be generally in labeling is a -- is a regulatory issue.
Q. And this is getting back to my original question, which we're not -- I'm not able to get a direct answer to, but maybe we'll get to now because I think we've gotten down to the point where there's very little room on either side, so let's try it one last time.
When the regulatory professional responsible to list the risks in the Prolift IFU interacted with Medical Affairs and got information from Medical Affairs, what is the decision that the regulatory professional was making with regard to whether or not risks needed to be included?
A. Whether those risks that Medical Affairs proposed for labeling needed to be included?

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Q. Yes, let's go to that question.
A. I think that Regulatory Affairs people generally rely upon the Medical Affairs people to identify the risks regarding the particular product, so they would pass that through, in a sense, generally, to the labeling.
Q. So if Medical Affairs at Ethicon communicated to Regulatory Affairs that a specific warning needed to be provided in the IFU, Regulatory Affairs would need to make sure that that warning would be included; correct?
A. I think eventually --
MS. KABBASH: Objection.
THE WITNESS: -- yes.
BY MR. SLATER:
Q. Well, when you say eventually, let me ask the question this way: If, hypothetically, two months before the Prolift even went on the market, someone in Medical Affairs drafted a specific warning and said, this warning should be included in the Prolift IFU, the Regulatory Affairs person would be responsible to make sure that that warning would be included before the device would be marketed; correct?
A. Well, I think, generally, that would

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be important, yes. As far as -- as far as the development of the IFU and wherewithal getting the IFU printed and whatnot -- the IFU could have been already final printed. There may be situations where you might have to wait until next edition to get it in, for example.
Q. Let me ask you this: Do you think it's acceptable if Ethicon knew two months before the Prolift even went on the market that a warning had been recommended by Medical Affairs to be included -- rephrase. I'm going to ask the question differently. Let me ask you a hypothetical.
I'd like you to assume that two months before the Prolift began to be marketed in 2005, someone in Medical Affairs prepared a specific warning and said, this needs to be included in the Prolift IFU.
I'd like you to assume that the Research and Development project leader and the Regulatory Affairs project leader for the Prolift device saw the warning and that the project leader made the decision, I'm not going to include this warning because I don't want to reprint the Prolift IFUs which have already been printed.
You think it's acceptable from a

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regulatory perspective for that Prolift to go on the market with that IFU without that warning; is that your testimony?

MS. KABBASH: Objection.

THE WITNESS: I think -- given my druthers, I think I'd try to understand what was going on specifically at that point in time, what -- what were the limitations presented to Regulatory Affairs.

You try and get information in the final printed labeling. I've seen many times when people have to wait till next edition to get stuff in, because at the last moment, it's very difficult to stop the train. Everything's in motion and packages are in boxes and things are moving.

So it's difficult to do some things sometimes.

BY MR. SLATER:

Q. Coming back to my question, in simple terms, based on the specific hypothetical I gave you, you would agree with me that from a regulatory perspective, the right thing to do would be to include the warning and print new IFUs so that from day one, doctors would know that information; correct?

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MS. KABBASH: Objection.

THE WITNESS: You'd -- you'd want to reprint IFUs as quickly as possible considering all the wherewithal to get that done in a company; and there's other ways, also, to get information like that out to professionals in the interim.

BY MR. SLATER:

Q. From a regulatory perspective -- the fact that from a business perspective, the company may move slowly when they need to make changes to documents and the fact that the company may want to save money and not have to reprint IFUs and throw away IFUs, that should not matter to the regulatory professional, because the regulatory professional's job is to make sure that if Medical Affairs says a warning needs to be in the IFU, the warning needs to be there. That's a correct statement. Right?

MS. KABBASH: Objection.

THE WITNESS: Well, I think if the warning needs to be in there, it needs to be in there. How quickly it needs to be in there, how expeditiously, well, that brings in all the other wherewithal in getting IFUs out there.

And you have to understand, sir, that certain IFUs are already printed, they're in boxes,

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the product's sterilized. It's -- it's not as easy as you might think.

BY MR. SLATER:

Q. Well, regardless of the fact that it may be easy or not easy and it may be expensive to reprint the IFUs, the regulatory professional's job is to make sure that the necessary warning goes out with that device from day one so that there aren't any doctors who don't have that information when they make decisions on whether or not they're going to put a Prolift in a woman's body. That's a true statement; correct?

A. I -- I think, yes, generally, if the -- if there is a medical concern, you want to get that information out. If you can't get it in the IFU, what alternatives exist to get that information out, during training, during other vehicles, to get that information to doctors who will be using your product, dear doctor letters, whatever the case is.

Q. The federal -- I'm sorry.

The federal regulations that apply to the Prolift required that if Ethicon was aware -- rephrase.

The FDA regulations that apply to the Prolift required that, under my hypothetical, that

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IFU include that warning that a Medical Affairs person said needed to be included in that IFU. And even if it would have been time consuming and may have delayed the launch of the device and even if it may have been expensive and required some packaging and some labels to be thrown away, the company needed to take the necessary time; the company needed to pay the necessary dollars to make sure that IFU disclosed that risk; correct?

MS. KABBASH: Objection.

THE WITNESS: Well, I agree with your final part, which is, you need to disclose the risk. I think that the process of doing that can be problematic depending on what's happening in the plant, and there's other means to disclose information beyond the IFUs.

Does it have to get in there ultimately? Yes, I think so, as -- as new editions come along, because during the course of three to six months, other issues may come up. You can't be reprinting IFUs every two weeks and trying to get those things out there. That's just -- it's just nonsense.

You've got to -- you've gotta have a system, a process, that's orderly to try to get

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these things out.
BY MR. SLATER:
Q. Is there an FDA regulation that says that if the company is aware of a risk that its Medical Affairs Department wants included in an IFU, that it's acceptable to not include that risk and to provide that information to doctors in another way? Is there a regulation that actually says that?
A. The labeling regulations are -- are extremely brief, so the answer is, no --
Q. Is there a regulation that says what I just said?
MS. KABBASH: Objection; asked and answered.
THE WITNESS: I just answered no, sir.
BY MR. SLATER:
Q. Going back again to my hypothetical, if that occurred and Ethicon failed to include that warning in the IFU, either at launch or in the next three years after launch, you would agree with me that Ethicon violated its regulatory obligations with regard to that warning that was not provided; correct?
A. Well, first of all, the regulatory

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obligations in the labeling regulations simply says you have to include adverse effects. That's all it says.
Now, another part of your question -- it was a multiple-part question, I think. Another part of your question is --
Q. Let me reask it then.
A. Okay.
Q. I'm going to reask the question then.
A. Okay.
Q. I don't want to have -- I honestly -- I don't want to go into tangents. I want to ask you a specific question.
With regard to my hypothetical, if the warning was not included at launch of the Prolift and was not ever included in the IFU for the Prolift at any time, you would agree with me that that would be a regulatory violation by Ethicon; correct?
A. Well, if it was never in the labeling and should have been in the labeling, I think that's an issue, yes. There may be --
Q. That's my question.
A. Well, there may be reasons why that's the case, without knowing the background there. But

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assuming that it's medically important, it should be in the labeling at some point and it never got in the labeling, that could be a problem.
Is it a violation? Well -- well, I guess that's subject to some assessment in regard to what violation I would append to that.
Q. It would clearly be a regulatory violation; correct?
MS. KABBASH: Objection.
THE WITNESS: You're saying would it be a misbranding?
MR. SLATER: Sure, if that's the definition. That would be misbranding; correct?
THE WITNESS: I think that requires some analysis before I would say that, but the -- the premise of your question --
MR. SLATER: As --
THE WITNESS: Let me finish.
MR. SLATER: Let me ask you this -- go ahead, sorry.
THE WITNESS: The premise of your question was, I think, that it should be in there and I -- I'm agreeing with you, if medically it's important, Medical Affairs thinks it should be in there, there's nothing that's changed in regard to

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that adverse effect or the need for that adverse effect, it's not been encompassed by other language, for example, or whatever else I might conjure up, if it still needs to be in there three years later, I think three years later is -- can be problematic, yes.
BY MR. SLATER:
Q. When you say problematic, you mean it would be a regulatory violation; correct?
A. It could be, yes.
Q. It would be; correct? Not could be; it would be; correct?
A. Well, that incurs medical assessment whether it would -- FDA would take regulatory action on that, so it -- I can't say with certainty, but it could be.
Q. In this case, you said you would need some analysis on such a question; correct?
A. Yes.
Q. Okay.
You have not performed such an analysis as you sit here now with regard to any of the warnings or proposed warnings for the Prolift or the Prolift+M; correct?
A. From a -- from a regulatory point of

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view, I've -- from documents, I've identified regulatory issues in terms of labeling, but that's -- that's the extent of my testimony, regulatory issues regarding labeling.

Q. The analysis that you would need to perform in order to determine -- well, rephrase.

With regard to my hypothetical again, you testified it would take you some analysis to determine what regulatory issues and violations would be encompassed by that hypothetical.

Am I accurate that as you sit here now, you have not performed such an analysis with regard to any issues with regard to the Prolift or Prolift+M?

MS. KABBASH: Objection.

BY MR. SLATER:

Q. Correct?

A. Well, in regard to the specific instance we began with, no, I have not. In regard to other labeling aspects, I've seen documents where we can talk about regulatory issues regarding labeling.

Q. As you sit here now, did you see any instances -- well, rephrase.

Based on all the information you read

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-- well, let me take a step back.

You said something earlier that if a risk was deemed by Medical Affairs to be a medically important risk, it would need to be in the IFU; correct?

A. I think so. There might be justification that I'm just not aware of or -- that -- that may counter that, but generally, yes.

Q. You would agree with me that if Medical Affairs at Ethicon deemed a risk to be a, quote, unquote, medically important risk, that it would need to be included in the IFU; correct?

A. Okay. We're kind of coming full circle and I said, yes, ultimately.

Q. The answer to my question is "yes"; correct?

A. At some point in time, yes.

Q. When you say "at some point in time," as quickly as feasible, that warning would need to be given in the IFU; correct?

A. I think that's the case, yes.

Q. So to the extent that the jury in this case would determine that Ethicon Medical Affairs was aware of a risk that the jury would believe would be medically important, because

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they're the ultimate fact-finders in this case, if that risk were not included in the IFU at any time, you, as a regulatory expert, would say, well, then that's misbranding; correct?

MS. KABBASH: Objection; calls for a legal conclusion regarding the jury's finding.

THE WITNESS: Well --

MR. SLATER: The answer to my question is "yes." Right?

THE WITNESS: If, again, the -- your criteria were, is it medically necessary as a decision of Medical Affairs, it should be in the labeling at some point in time, I've -- I've already said yes.

BY MR. SLATER:

Q. Well, again, the standard for what gets included in the labeling for a medical device is not does Medical Affairs think that the risk should be disclosed; the standard is, from a regulatory perspective, if Medical Affairs recognizes a risk to be what you would call, quote, unquote, medically important, then Regulatory Affairs has to make sure that risk is disclosed; correct?

A. I believe that's --

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MS. KABBASH: Objection.

THE WITNESS: -- also probably part of Ethicon's process, so, yes, ultimately.

BY MR. SLATER:

Q. Just without the lead-in to the answer, the answer to my question is "yes"; correct?

A. Yes, ultimately.

Q. Did you in your review of the materials attempt to identify medically important risks that were known to Ethicon Medical Affairs that were not disclosed in the Prolift or Prolift+M IFUs? Did you make an effort to determine that question?

A. I -- I haven't -- that raises medical opinion issues. I've identified -- read deposition testimony about medical opinions on what's in the labeling versus what's not in the labeling, but those are primarily medical opinions, so I don't opine on those specifically.

Q. You drew no opinion and did not analyze that specific question; correct?

A. That's correct.

Q. I've asked you a bunch of questions about the IFU. With regard to the patient brochure, the same standard would apply. If a risk is a

medically important risk, it should be disclosed from a regulatory perspective in the patient brochure; correct?
A. Well, you're saying "should."
Q. It's required by the regulations; correct?
A. Well, there's nothing in the labeling regulation for medical devices that even talks about patient brochures, so --
Q. But if a company decides to put a patient brochure out, those standards would apply; correct?
A. Anything a company does is entirely voluntary in regard to the regulations. There's no regulation regarding patient brochures for medical devices.
Q. Here's my question -- well, let's take a step back.
A company is not required to issue a patient brochure based on the FDA regulations; correct?
A. Correct.
Q. However, if a company decides to issue a patient brochure, for example, the patient brochure for the Prolift, then the standards that we

discussed with regard to the IFU and the disclosure of risks would apply to the patient brochure, because now the company has affirmatively put out that patient brochure to give information directly to patients, so it must adhere to that standard; correct?
A. I wouldn't say that's the case.
Q. So you think that if the Prolift IFU fails to disclose a medically important risk to a patient -- rephrase.
Is it your testimony that -- that if the Prolift patient brochure fails to disclose a, quote, unquote, medically important risk, you think that's acceptable from a medical -- from a regulatory perspective?
MS. KABBASH: Objection.
THE WITNESS: What I'm saying is, the regulations don't speak to patient brochures and there's no regulatory requirements listed for patient brochures. I think where patient brochures come into play is -- in FDA's mind is, they're an element in the informed consent process.
BY MR. SLATER:
Q. Well, you know for a fact that the FDA considers patient brochures to be labeling.

You've testified to that effect in prior deposition testimony; correct?
A. Yes.
Q. And, therefore, the labeling requirements of the FDA regulations apply to a patient brochure if a company like Ethicon decides to issue a patient brochure; correct?
A. No. The labeling requirements speak to prescription use labeling, labeling for doctors in this case. The labeling regulation doesn't speak to patient brochures.
MS. KABBASH: Adam, could we plan on --
BY MR. SLATER:
Q. Are you -- is it your --
MS. KABBASH: Adam, I'm sorry to interrupt you.
MR. SLATER: I'm sorry?
MS. KABBASH: Could we plan on a break in the next couple of minutes? Because we've been going somewhere between --
MR. SLATER: Sure.
MS. KABBASH: -- an hour and 15 minutes and an hour and a half, so I would appreciate that.

MR. SLATER: All right. I'll try to ask a couple more questions and then we'll take a break.
MS. KABBASH: Okay.
BY MR. SLATER:
Q. It is not acceptable for Ethicon to mislead a patient about any medically important information in a patient brochure. You would agree with that from a regulatory perspective; correct?
A. I think that's the case, yes.
Q. If, in fact, the Prolift patient brochure was misleading with regard to any medically important risks, that would be improper from a regulatory perspective; correct?
A. Yes.
Q. If information was provided in the Prolift patient brochure that was unsupported by any foundational data -- and I'm talking about claims with regard to the attributes of the device -- that would be improper from a regulatory perspective; correct?
A. And your premise was lack of foundation for the claim or --
Q. Yes.
A. Well, I think generally lack of

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foundation is a problem in any statement, in any form of labeling.
Q. And with regard to my question regarding a patient brochure, the answer's "yes," correct, it would be improper?
MS. KABBASH: Objection.
THE WITNESS: Well, improper versus is it a violation. Are you asking my mindset regarding whether it's proper or improper or are you asking a regulatory question here?
BY MR. SLATER:
Q. From a regulatory perspective, it would be improper to do so; correct?
A. Well, you'd have to connect it to -- to a violation. You have to have a hook there; in other words, companies can -- can do what they care to unless there's a -- there's some limitation in regulation.
Q. Well, a company like Ethicon cannot make a claim in a patient brochure that it cannot support with any foundational data; correct?
MS. KABBASH: Objection.
THE WITNESS: I think -- I think that would be a problem. Now what violation I would attach to that, I'd have to think about that, how

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I'd construct a violation.
BY MR. SLATER:
Q. You have not done that analysis with regard to any of the Prolift or Prolift+M patient brochures; correct? You haven't conducted that analysis as you sit here now; correct?
MS. KABBASH: Objection.
THE WITNESS: "That analysis," specifically what?
MR. SLATER: You have not analyzed whether any of the claims made in any of the Prolift or Prolift+M patient brochures lacked foundation and therefore were inappropriate from a regulatory perspective. You haven't analyzed that question; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, I just want to make sure we're talking about statements in labeling versus claims, so I guess you'd have to tell me a couple items that -- that you're talking about so we're on the same page.
BY MR. SLATER:
Q. If a claim was made -- well, rephrase.
Is there any claim or statement that

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was made in either -- well, rephrase.
Was there any claim or statement made in any of the Prolift or Prolift+M patient brochures that you analyzed to determine whether or not there was a foundation for that statement or claim?
A. Only in the regulatory sense that it may have been in prior -- in predicate labeling or submitted in the 510(k)s or something of that sort. That would be the only assessment --
Q. But you did no analysis as to the -- but you did no analysis as to the validity or truthfulness of any of the statements or claims in any of those patient brochures; correct?
A. Inasmuch as it would require a technical/engineering/medical assessment, no.
Q. So it's something you did not analyze or opine on; correct?
A. Not in regard to those aspects, no.
MR. SLATER: Okay. Why don't we take a break.
MS. KABBASH: Okay.
THE VIDEO TECHNICIAN: The time now is 11:47 --
MR. SLATER: Come back in about ten minutes?

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MS. KABBASH: Yep.
THE VIDEO TECHNICIAN: -- we are going off the record.
(A recess was taken from 11:47 a.m. to 12:06 p.m.)
THE VIDEO TECHNICIAN: The time now is 12:06. We are back on the record.
BY MR. SLATER:
Q. Okay.
With regard to what Ethicon Regulatory Affairs did in making decisions as to what would be in the labeling for the Prolift and Prolift+M, did you actually analyze that process of what the regulatory professionals actually did to make their decisions and what information they considered?
A. I didn't separately analyze. Certainly evaluated -- I saw, rather, read deposition testimony on what they -- what they had done, what they had considered, interactions with Medical Affairs, so I read that testimony.
Q. Am I correct that you did not form any opinions with regard to whether or not the decisions made by the regulatory professionals as to what was included in the labeling for the Prolift

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and Prolift+M were correct or incorrect decisions; you didn't analyze that or opine on that; correct?
A. I don't think I have any opinions like that, no.
Q. You're familiar with the design control process also known as the risk management process; correct?
A. Well, it's actually -- you actually just talked about two different things that are different but related.
Q. Okay.
There's something known as design control and something known as risk management, and these are processes that a company is required to go through before marketing a medical device; correct?
A. Design controls, yes. Risk management, generally no, not a requirement. The only requirement in regulation concerns the need for a risk analysis.
Q. Okay.
Prior to the marketing of a medical device, a company like Ethicon must go through -- well, rephrase.
Prior to marketing a medical device, the manufacturer must go through a process of design

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control and risk analysis; correct?
A. Yes. A risk analysis is actually part of design control.
Q. The regulations do not specifically set forth what the design control procedures and risk analysis procedures must be. It just tells the manufacturer, you need to implement these regulations by going through a process that will answer certain questions so that you can determine these answers and then be able to market your device; correct?
A. I think generally yes --
MS. KABBASH: Objection.
THE WITNESS: -- the regulations outline elements of the design control process and then the company implements those regulations with -- with processes, procedures, SOPs.
BY MR. SLATER:
Q. Once a company puts in place processes, procedures, standard operating procedures, those sorts of things, to implement design control and risk analysis, the company needs to adhere to those processes and procedures; correct?
A. Yes.

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Q. You did not analyze or form any opinions as to whether or not Ethicon actually implemented all of the processes and procedures that were put in place with regard to the Prolift and Prolift+M; correct?
A. Well, I didn't receive all processes and procedures. I did receive a number of processes and procedures which I did review. You do see elements of how those are implemented to the extent possible.
So to that extent, I did assess the processes and their implementation.
Q. Your assessment included noting that certain processes and procedures were put in place and that documentation of those processes and procedures being applied existed. You noted that in your review; correct?
A. Yes.
Q. What you did not evaluate, if I understand correctly, is whether or not Ethicon fully implemented those processes and procedures in the sense of actually doing all of the work necessary to properly go through each step; is that a fair statement?
A. Yeah, I think that's a fair

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statement. That would probably -- probably require an inspection of the facility and evaluation of all the documents.
Q. And that's something you did not do; correct?
A. That's correct.
Q. One aspect of the design control and risk analysis process before the Prolift was marketed was the DDSA and FMEA process; correct?
A. Yes.
Q. You did not analyze the question of whether or not Ethicon adequately analyzed all of the risks known to Medical Affairs with regard to the Prolift as part of the DDSA and FMEA process; correct? It's not something you analyzed or opined on; correct?
A. Not from a technical/engineering perspective, no; but from a regulatory perspective, I evaluated those processes, evaluated the output of those processes, determined that they applied those processes; but as far as any specific engineering/medical assessment, I didn't do that sort of assessment.
Q. You noted that the DDSA and FMEA processes were applied, but you did not form any

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opinions as to whether or not they were applied in such a way that all of the risks that needed to be evaluated actually got evaluated. True statement?
A. I'd have to turn to my report to see with precision exactly what I've said about that.
Q. Well, as you sit here right now, you do not have any opinion one way or the other as to whether or not the DDSA and FMEA processes for the Prolift or the Prolift+M evaluated each of the medical risks that needed to be evaluated; correct?
A. Well, if you're asking if the -- did I do a medical assessment of the DDSA or FMEA, no, I didn't do that. That's the answer to your --
Q. That's what I'm asking.
A. And I just said, no, I didn't do that.
Q. And -- okay.
And, in fact, the only way to answer my question would be to do a medical assessment of what information was available to Medical Affairs and then match that up against what was evaluated in the DDSA and FMEA processes to see if the risks were adequately evaluated in that process; correct?
A. You'd have to evaluate it, yes, from a medical and an engineering aspect to fully

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determine the technical sufficiency of the DDSA and that -- of course, that's based on --
Q. And that's not --
A. That's based on information also that would have been available to Ethicon at that point in time when they were constructed.
Q. And that's not something you did, obviously; correct?
A. No, I did not.
Q. If there was a, quote, unquote, medically important risk known to Medical Affairs and Medical Affairs did not make sure that that risk was assessed as part of the design control and risk analysis process before the Prolift was marketed, that would be a violation of the design control regulation; correct?
A. Well, I guess I'd have to see how that particular risk -- whether it was considered or considered tangentially or in some other way.
Risk analyses sometimes don't exactly line up as you look back at risk analyses, but the considerations going -- moving forward when they're originated can have broad considerations that may encompass what you're talking about.
So I -- I just can't say.

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Q. You don't form an opinion one way or the other on that?
A. No, not -- you know, if you have a specific situation, but I -- no. I think what it requires is a medical assessment/engineering assessment of the DDSA or FMEA to see what was listed, what was considered, why it was considered, those aspects, for example.
Q. And that's not an analysis you performed with regard to the Prolift or Prolift+M; correct?
A. That's correct.
Q. One of the things that is done in the DDSA -- well, let me ask you a question just so we're on the same page.
When you talk about the DDSA, you include within that the FMEAs; correct?
A. It's an element, typically an element of that, yes. And there's different FMEAs. There's design application, manufacturing, or process FMEAs.
Q. As part of the DDSA/FMEA process, there are lists made on tables of each of the risks that were actually evaluated, and they're denoted as hazards and harms; correct?
A. Yeah, at the front end usually

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there's a description of discussion of hazards, and later on those hazards are evaluated in the FMEA as far as mitigations.
Q. The reason that the hazards and harms are listed is so that if one wants to know what was evaluated, one can look at those lists and confirm exactly what was evaluated. That's one of the reasons to list them; correct?
A. Yes, information that's considered at that point in time when it's constructed.
Q. If there was a, quote, unquote, medically important risk that was known to Medical Affairs and Medical Affairs knew that this would happen to some women due to the Prolift and knew that if it happened to a woman, it would cause very severe permanent damage to her vagina and pelvis and that risk was not evaluated as part of the FMEA/DDSA process, that -- if that hypothetical is accurate, that would be a violation of the design control regulations; correct?
A. Well, I think -- difficult to say yes or no. I think, again, the medical, engineering, technical assessment of that, the DDSA/FMEA may have incorporated some of that in a broader sense. I just can't say specifically.

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Q. If based on the way Ethicon set up its design control process, if my hypothetical is accurate and that risk is not specifically described in the DDSA or FMEA documents, it's not listed, it's not specifically described, would -- that would mean that it was not evaluated based on the literal terms of that process; correct?

A. Well, I think you're expecting more than what many, many DDSAs/FMEAs incorporate. DDSAs and --

Q. I'm only asking about this process -- hang on. I'm only asking about this process for the Prolift device and the Prolift+M device.

The answer to my question would be yes, if it's not listed, it wasn't evaluated, based on the technical terms of how that process is supposed to be implemented; correct?

A. I can't say with certainty. I think part of that requires a medical/engineering assessment of what was evaluated and what is encompassed within those hazards that are discussed in the DDSA/FMEA.

And so many things --

Q. You're not, again -- and I --

MS. KABBASH: Adam, I think you --

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MR. SLATER: I'm sorry. I didn't mean to interrupt you.

MS. KABBASH: -- were cutting off his answer. Just let him finish.

THE WITNESS: So many things may be --

MR. SLATER: Yeah, I didn't mean to do that. I apologize.

THE WITNESS: Yeah, so many things may be generally considered under DDSAs/FMEAs. As products are marketed and the company comes back to the FMEAs, things -- things may get more refined, more detailed, but, typically, original DDSAs/FMEAs are not extremely detailed in regard to hazards in all respects.

BY MR. SLATER:

Q. To the extent a medically important risk was actually known to Medical Affairs at Ethicon, Ethicon was required to evaluate that risk through the DDSA/FMEA process before marketing the Prolift; correct?

A. What -- not precisely. What they're required to conduct is a risk analysis. Then it becomes a --

Q. And that risk has to be evaluated.

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Right?

A. Well, that's --

Q. That's the way the process was set up. If the medically important risk was known to Medical Affairs, it needed to be evaluated; correct?

A. Well, what I said is what the regulation calls for. Now, as far as any specific hazard/risk, then you get into technical assessments and deliberations of whether the DDSA/FMEA should have included this, would have included this. So that that -- that's -- you're starting to get into the weeds of differing opinions.

Q. If there was a medically important risk known to Medical Affairs before the Prolift was even marketed and it's a risk that they knew was going to occur to some women and cause severe permanent harm to women when it occurred, if that's the fact, then it was required that that risk would be evaluated in the design control/risk analysis process; correct?

A. I would -- I would say generally a hazard of that type either generally -- probably more generally would be an ingredient of a DDSA/FMEA.

So I -- I think that's about as far

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as I can go with that, so -- the regulations don't -- don't get specific about that and assessments of risk analyses, you get differing opinions from experts, clinical/engineering experts, on whether the DDSA/FMEAs were adequate or not adequate at a point in time.

Q. Well, the design control regulation sets forth certain issues that have to be addressed and then tells the company you have to put in place a process to evaluate these issues; and the regulation says, if you don't do that, you don't implement procedures that are adequate to answer these questions and you don't, for example, evaluate known medically important risks that can result from the use of this medical device, that would then be a violation of the design control regulation; correct?

A. I'd have to think about that, because, again, the regulation just talks about risk analysis and goes no further. So typically the violations that are assessed based on that provision is the presence or absence of a risk analysis.

Once you get into the weeds as far as the ingredients of the risk analysis, it gets more muddled, because then you get into medical/engineering differences of opinion.

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FDA typically didn't get into the weeds on that.
Q. When you talk about getting into the weeds, with regard to the Prolift and Prolift+M, you did not, quote, unquote, get into the weeds of the questions regarding these devices; correct?
MS. KABBASH: Objection.
THE WITNESS: In regard to the DDSAs/FMEAs, no, not from a medical/engineering perspective, no. I viewed them, evaluated that the procedures were there, that in my expertise, they appeared to be generally consistent with industry standards and FDA's expectations, and found them substantially compliant.
BY MR. SLATER:
Q. You found that the procedures that Ethicon put in place were compliant with what procedures were supposed to be put in place, but you offer no opinions with regard to the actual application or conclusions drawn through those processes; correct?
A. That's correct. My report doesn't go into detail on the FMEAs -- or DDSAs/FMEAs.
Q. In your report, you talk about something called an unacceptable risk in the context

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of risk management. What is an unacceptable risk?
A. Well, now we're talking about risk management and risk management is a -- is a broader process. That actually -- one part of it is risk analysis, but it's only one part.
Risk management -- sorry for the long-winded response, but risk management and the standard upon which it's based talks about the various elements of risk management. One part talks about assessment of risks, unacceptable risk, and what you do about them.
Q. How do you define an unacceptable risk?
A. Well, I think I've referred to the risk management standard. It's -- I'll just say that generally it's a -- it would be a risk that cannot be tolerated in the final product, but should be mitigated or should be -- if cannot -- if it cannot be eliminated, is it acceptable from a benefit/risk point of view.
Q. Wouldn't an unacceptable risk be a risk that cannot be mitigated; due to the fact it cannot be mitigated, that risk is deemed to outweigh the benefit and, thus, the device should not be sold with that risk existing; correct?

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A. Well, I think I'd like to turn to my report to see the context of that statement.
MS. KABBASH: You can do that you if need to.
THE WITNESS: Just to make sure --
MR. SLATER: Page 12.
THE WITNESS: Okay.
(Pause.)
THE WITNESS: Yes, that -- I was talking about risk analysis in regard to unacceptable risk. And so your question, again, sir, was?
MR. SLATER: I'll ask the court reporter just to read it again, because I tried to specifically define an unacceptable risk; and then after she reads it again, tell me if you agree with that definition.
- - -
(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: Well, I think in regard to risk analysis, the answer is, yes, that if a risk is unacceptable and you've applied risk mitigation factors, still unacceptable in terms of after risk

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mitigation, and then the risk/benefit -- the benefit/risk analysis demonstrates that it is still unacceptable, then it's unacceptable.
BY MR. SLATER:
Q. And in that circumstance, that medical device should not be sold; correct?
A. Probably should not be sold.
Q. If, in fact, there were any unacceptable risks, as we've just defined it, with regard to the Prolift, the Prolift never should have been marketed; correct?
A. No. What I'm saying is, after the benefit/risk decision making has been accomplished where you -- the company weighs the residual risk of the product against a potential benefit of the product, if the decision is made, yes, we think this should move forward, then the product moves forward.
Q. Well, here's what I'm asking you: If objectively viewed, the information available to Medical Affairs would have led to a finding that there was one or more unacceptable risks with the Prolift, as you've defined an unacceptable risk that would require a device not to be marketed, then the Prolift should not have been marketed; correct?
MS. KABBASH: Objection.

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THE WITNESS: Well, this is after the benefit/risk decision making of the company, because there may still be --
BY MR. SLATER:
Q. Well, here's what I'm asking. I'm not deferring -- I don't want to defer to what the company -- we know the company made a decision to sell the Prolift. Okay? But as you know, I think that decision was the wrong decision. That's one of the reasons we're here, and that's why I'm going to try cases against Ethicon with regard to the Prolift and Prolift+M.
So deferring to the decision made by Medical Affairs, you understand one of the things I'm going to tell the jury and try to prove to the jury is that they made the wrong decision. So I'm asking you an objective question as opposed to just deferring to the decision they made.
I just wanted to explain that to you so you understand the context in which I'm going to now ask this question.
So here's my question: If objectively viewed, there were one or more unacceptable risks with the Prolift, as you've defined an unacceptable risk, following the entire

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risk/benefit analysis, the risk was -- if there was still a risk that, objectively viewed, would be deemed an unacceptable risk, then the Prolift should not have been marketed; correct?
A. Hang on just a moment.
(Pause.)
THE WITNESS: I think that in the -- in the final analysis, after a benefit/risk decision process is conducted, that the final decision of the manufacturer is, any residual risks are acceptable and we're going to move the product forward.
BY MR. SLATER:
Q. But if objectively -- if an objective analysis of the information available to Ethicon would lead to the conclusion that there were one or more unacceptable risks, after mitigation, after risk/benefit analysis, there was still one or more unacceptable risks, then the Prolift should not have been marketed; correct?
MS. KABBASH: Objection.
THE WITNESS: I -- I guess I'm getting a mental disconnect here, because the -- the result of the benefit/risk decision is to assess any residual risks and determine whether or not to move the product forward, meaning we think this product

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is acceptable to move forward; that the residual risks are acceptable, albeit they're there, but they're acceptable because the benefit outweighs the risk.
So they may begin as unacceptable risks. They're mitigated, and then the final decision is they're -- the product's acceptable on a benefit/risk decision making.
So if -- it just -- there seems to be a disconnect that there would be residual unacceptable risks after a benefit/risk decision.
BY MR. SLATER:
Q. There are manufacturers who will go through this analysis to determine if there is a unacceptable risk or risks with a device; and sometimes they will determine, you know what, there's a risk that we can't mitigate by redesigning, we can't mitigate with warnings; and with this risk present, the risk outweighs the benefit and we're not going to market this device. That occurs. Right?
A. Yes.
Q. Okay.
If, in fact, an objective person or persons were to analyze the information that was

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available to Ethicon before the launch of the Prolift and if that objective analysis determined that there were unacceptable risk or risks with the Prolift that could not be mitigated by redesign, could not be mitigated by warning, and that the presence of this residual risk tipped the balance such that the risk outweighed the benefit with the Prolift, if that was the analysis and if that's the proper analysis objectively viewed, then the Prolift should not have been marketed. Based on that hypothetical, you would agree; correct?
MS. KABBASH: Objection.
THE WITNESS: The responsible party to make this decision is Ethicon, so who's this objective party you're talking about?
MR. SLATER: Well, I'm asking you from a regulatory perspective what their obligation was. And you agree with me the obligation objectively viewed from a regulatory perspective would be that if that was the final conclusion, then the Prolift should not be marketed; correct?
THE WITNESS: If the responsible party at Ethicon in regard to marketing the product, after a risk assessment is conducted and the finding -- and the finding is -- the benefit/risk decision

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is, this product is unacceptable, and that's the party that has control at Ethicon over that decision making, it doesn't -- it doesn't connect with me that they would market it in that case. The decision needs to be, this is an acceptable product from a benefit/risk decision.
BY MR. SLATER:
Q. If the risk -- well, rephrase.
The answer would hold the same for the Prolift+M; correct?
A. Yes.
Q. The answer would hold the same for any medical device; correct?
A. Yes.
Q. If at the end of the risk analysis, it is determined as a matter of fact that the risk of a medical device outweighs the potential benefit of the medical device, that medical device should not be marketed; correct?
A. Are you talking about information that comes to bear afterwards or what?
Q. I'm talking about information that's available before the product even goes on the market.
A. Well, again, the process is as I've

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stated: Decision of the responsible party at Ethicon to make that decision based upon a benefit/risk analysis.
Now, are you saying that additional information comes to bear or -- or what?
Q. No, it's a very simple question. I'm not even asking specific to Ethicon.
With regard to any medical device manufacturer, if an objective analysis of the available information indicates that the risk outweighs the benefit, that medical device should not be marketed. You'll agree with that proposition; correct?
A. Yeah, in any company, if the responsible party makes the decision that the risk outweighs the benefit, that's -- that's the outcome, output of the benefit/risk decision-making process -- that's one of the outcomes.
Q. If -- I apologize. If after a -- rephrase.
If after a medical device goes on the market, the information becomes available to the manufacturer indicating that the risk outweighs the benefit, the manufacturer should withdraw that medical device from the market; correct?

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A. Well, again, you're talking about a process, so they'd have to go through this process to make that decision, and the responsible party --
Q. And once they went through that process -- and once they went through that process, if it was deemed objectively that the risk outweighed the benefit, the device should be withdrawn from the market; correct?
A. I think that's the case, because risk management is an iterative process.
Q. Risk management, is that -- well, rephrase.
The process I just described to you is the risk management process or at least part of it, and that's something that goes on every day after a device is put on the market; correct?
A. Right, manufacturers receive new information. They have to digest it and consider it in terms of the product, whether it's every day or periodically, whatever the process is.
Q. You've listed Anne Weber's report as one of the things you reviewed. Did you read her entire report?
A. All 500-some pages?
Q. Yeah.

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A. Yes.
Q. You read her trial testimony as well, I see, on this updated list of materials; correct?
A. Yes.
Q. You understand that Dr. Weber has offered the opinion that when the entire analysis is performed of the information that was available to Ethicon, in her opinion, the risk of the Prolift outweighed the benefit and it should not have been marketed.
You know she holds that opinion; correct?
A. Yes.
Q. If, in fact, the jury agrees with Dr. Weber and they make that factual finding that she's correct, you as a regulatory expert would say -- if that's the fact, if we hypothetically assume that Dr. Weber is correct, then you would say, based on that fact, the Prolift should not have been marketed; correct?
MS. KABBASH: Objection; calls for legal conclusion as to the implications of what a jury finding may be.
MR. SLATER: That would be your opinion. Right?

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THE WITNESS: That's the opinion of the jury. Whether or not I agree with Dr. Weber --
MR. SLATER: That's not what I'm asking you. I haven't asked you that yet, so I'll ask you it again.
BY MR. SLATER:
Q. Coming back to my question, if the jury agrees with Dr. Weber -- that's the foundation. That's my hypothetical for you -- if the jury agrees with Dr. Weber that the risk of the Prolift outweighed the benefit, then you as a regulatory expert, based on that factual foundation, would say, well, if that's the fact, then the Prolift should not have been marketed; correct?
MS. KABBASH: Same objection.
THE WITNESS: No, I -- I'd make -- probably make my own assessment of the facts. If I was still at FDA, that would be an independent finding by the jury and by Dr. Weber. They would assess the facts themselves.
BY MR. SLATER:
Q. As you sit here right now, under oath as an expert in the -- in this lawsuit, if, based on my hypothetical, the jury finds that Dr. Weber's opinion is correct and the risk outweighed the

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benefit, you as an expert in this case, based on that hypothetical, would agree that if that's the fact, then the Prolift should not have been marketed; correct?
MS. KABBASH: Same objection and asked and answered.
THE WITNESS: I mean, I respect the jury's opinion. I have a separate opinion in regard to those facts.
BY MR. SLATER:
Q. You have not offered an opinion one way or the other as to whether or not the risk of the Prolift was outweighed by the benefit or not. That's not something you've opined on in this case; correct?
A. I've not done a medical assessment of that benefit/risk decision process.
Q. So you're not -- you have no opinion on that issue. Right?
A. I think I just said no. Okay.
Q. Okay.
If at the trial of this case, the jury agrees with my expert that the risk of this medical device outweighed the benefit before it even went to market, if that's the fact -- I'm asking you

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to assume that fact -- then you would say, well, if that's the fact, this medical device should not have been marketed; correct?
MS. KABBASH: Objection as to legal conclusion, asked and answered.
THE WITNESS: I can't agree to that. I -- in all due respect to juries, I understand their -- their role. As an expert, just like Dr. Weber, we have our roles, too. So I can't say I would agree -- I -- I don't agree with her based upon what I've reviewed, notwithstanding what the jury may decide.
BY MR. SLATER:
Q. Let me explain to you how this works, and with all due respect to counsel, the question has not been asked and answered and it -- whether it calls for a conclusion or not that the jury's going to have to make a finding on does not preclude me from asking this question, okay, so let me -- let me try one more time with you.
If at the trial of this case, the jury finds that the risk of the Prolift outweighed the benefit, before the Prolift was ever launched -- I'm asking you to hypothetically assume, in fact, that the risk outweighed the benefit. You have to

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draw that assumption to answer this question -- if that's the fact that you assume, then the Prolift should not have been marketed; correct?
MS. KABBASH: Same objections.
THE WITNESS: I guess we're going to have a continuing disconnect here, because I think the jury's opinions and their basis for their decision don't necessarily impact my opinions regarding the product.
My opinions are what they are.
BY MR. SLATER:
Q. All right.
You've already told me you did not form an opinion based on the medical assessment of whether or not the risks outweighed the benefit or vice versa. Right?
A. That's correct.
Q. I'd like you to assume the following facts: I'd like you to assume that based upon a thorough and objective assessment of the information available to Ethicon Medical Affairs, an objective and reasonable Medical Affairs director would have concluded that the risk of the Prolift outweighed the benefit. I'd like you to assume that fact.
If that is the fact, the Prolift

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should not have been marketed; correct?
A. You -- I'll have to hear that question again. Sorry. If you could repeat that, somebody.
MR. SLATER: Sure. Read it back to him. No problem.
- - -
(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: Well, those aren't the facts of the situation. I think a reasonable Medical Affairs --
MR. SLATER: Move to strike. Move to strike. You're wasting my time, with all due respect. Please answer the question "yes" or "no."
THE WITNESS: I don't think I can answer "yes" or "no."
BY MR. SLATER:
Q. You're saying under oath that you can't answer that question "yes" or "no"?
A. That's what I'm saying, sir.
Q. Is it that you can't or that you're refusing to?
MS. KABBASH: Objection.

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MR. SLATER: Because you know that the answer to the question has to be "yes," so you just don't want to say it; and if that's the truth, you're obstructing this deposition, with all due respect, and not providing truthful testimony. I just want you to know that.
MS. KABBASH: Adam, are you done?
MR. SLATER: So I'm going to give you one last chance.
MS. KABBASH: No, no, no, before --
MR. SLATER: Can you answer my question, please? "Yes" or "no."
MS. KABBASH: Hang on, Mr. Utalowski. Adam, I'm going to strike the last statement of counsel. It is argumentative, harassing, and you don't have the right to tell the witness whether or not he's telling the truth. That is ultimately up to the jury, so I'm going to ask you to tone down your tone.
Feel free to answer the question.
MR. SLATER: Please answer my question "yes" or "no."
THE WITNESS: Please repeat the question.
- - -

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(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: I think that gets back to one of your other questions, which is, if the outcome of the decision process, benefit/risk decision is, the product is unacceptable, then the product shouldn't be marketed, and I already said yes.
BY MR. SLATER:
Q. Okay.
You did not evaluate whether or not the author of the clinical expert report for the Prolift did a thorough job in preparing that report, did you?
A. I don't think I opined that. I certainly reviewed -- looked at the report as a foundation regarding benefit/risk, but, no, I didn't -- I'm not a medical officer, so I didn't evaluate the sufficiency from a medical point of view of that report.
Q. I just want to come back, if I could, to the prior question before that about my hypothetical.
The same would hold true for the

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Prolift+M; correct?
A. Yes.
Q. The same would hold true for any medical device; correct?
A. Assuming I understand what "the same" means. Yeah, if the outcome of the benefit/risk decision by the responsible party at the company is, the product is unacceptable, then it's unacceptable and shouldn't be marketed.
Q. When the Prolift and Prolift+M went through the 510(k) process, the FDA relied on Ethicon to provide information; correct?
A. Well, that's partially true. I think in a broader sense, if you understand FDA, that, yes, the company submits an application. FDA brings to the table their experience and training and knowledge, also.
Q. As part of the 510(k) process for the Prolift and Prolift+M, the FDA relied on Ethicon to provide certain information; correct?
A. Yes.
Q. The FDA relied on Ethicon to provide truthful information; correct?
A. Yes.
Q. The -- rephrase.

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The FDA relied on Ethicon not to omit to provide any material information that was known to Ethicon that was relevant to the questions being asked by the FDA; correct?

A. You got words of "material" and "omitted." I think as a general statement, yes, that's the case. As --

Q. As far as --

A. Excuse me -- excuse me --

MS. KABBASH: He just wants to complete his answer.

THE WITNESS: As far as the information may be relevant, I -- you know, I think generally the question -- FDA poses questions. The company responds.

Whether that response is a paragraph, a page, or a textbook, I mean, that -- what is omitted, I think you'd have to look at each question and answer to kind of gauge whether something's material if it was not included.

BY MR. SLATER:

Q. To the extent that the FDA asked Ethicon for information and to the extent that Ethicon responded, the FDA was assuming that Ethicon would not omit to provide material information

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necessary to fully answer the questions with a request for information; correct? You'd agree with that general statement. Right?

A. As a general statement. Materiality has fuzzy parameters, but, yes, as a general statement.

Q. As part of the interaction between the FDA and Ethicon, the FDA assumed that Ethicon would disclose any problems or problematic issues that Ethicon knew about the Prolift or Prolift+M as opposed to waiting to see if the FDA would figure out to ask about those things; correct?

A. Well, I -- difficult question. I guess you're getting back to the point of materiality, how significant that might be, what impact it might have on the whole process, so I mean there's lots of --

Q. If the material --

A. Excuse me. I didn't finish -- so there's lots of things that a company has in its files regarding a product.

The FDA does not want to see all that dumped on it, so a company has to be somewhat judicious and selective in regard to what material it provides.

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Q. To the extent Ethicon had information in its possession that it knew the FDA did not know about and it knew that the FDA would likely place some emphasis on in evaluating the 510(k) submission, Ethicon was duty bound to provide that information to the FDA; correct?

MS. KABBASH: Objection.

THE WITNESS: You got a lot of parts to that one. Again, I -- I guess all I can say is that a company considers what information to submit from their complete files, considering what points they want to make to FDA, what data they think are going to be relevant to the decision-making process, and then they wait to see whether FDA believes that's satisfactory or whether FDA wants to see additional information.

So there may be additional information in their files that would not have been submitted. I -- I wouldn't be surprised one bit about that.

BY MR. SLATER:

Q. Well, you would not condone it if there was information in Ethicon's files that Ethicon knew could have a serious impact on whether or not the FDA would take certain action in response

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to the 510(k) and for Ethicon to hold that information in its file because it's afraid of a bad result. Right? You wouldn't condone that.

A. Again, it's materiality, how significant the information is, so it's kind of a, it depends, depending on what information you're talking about.

Q. Okay.

If Ethicon had in its possession information which you would define as material, significant information that would cast significant doubt on whether or not the 510(k) was the appropriate regulatory pathway for the Prolift, it was not acceptable -- if that existed, if that was the facts -- it would not be acceptable for Ethicon to not provide that information to the FDA; correct?

MS. KABBASH: Objection.

THE WITNESS: Well, if I thought it was material. Of course, the company isn't capable of reading my mind if I were at FDA, so, I mean, they're trying to identify what they think is material and to submit that information; and then FDA evaluates and then will ask questions, if necessary, to get to the points of materiality, that FDA thinks is material.

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BY MR. SLATER:
Q. With all due respect, I'm asking you the question as an expert in this case. You've put yourself on stage as an expert now. And you would agree with me that if there was information Ethicon had which you as an expert would define as material and significant information and that if that information was given to the FDA, would have had the very real possibility of causing the FDA to reject the 510(k) and forcing Ethicon to go to a PMA process, if that's the fact, you as an expert sitting here right now under oath would say, well, if that's the fact and Ethicon held that information back, that is completely unacceptable; correct?
MS. KABBASH: Objection.
THE WITNESS: I think the answer -- the answer is, yes. Let me just break it down a little bit. Would I, first -- it's a multipart question. The first part is what I think is material.
Of course, I'm not a clinician. I'm not a mesh biomedical engineer, so I'm not sure -- you know, my view what would be material might be rather limited, so -- but assuming something I thought was material was not provided, I guess I'd

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have a problem with that in regard to the submission.
MR. SLATER: Move to strike after the word "yes."
BY MR. SLATER:
Q. Are you aware that there are people who have serious concerns about the fact that people work at the FDA, interacting with manufacturers of medical devices and prescription drugs every day, and then people from the FDA who have done -- let me start over. I garbled the question.
Are you aware that there are people who are critical of the fact that people who work at the FDA for some number of years, making important decisions on whether or not medical devices and prescription drugs can be sold or what warnings are provided or other really important decisions with regard to patient safety, and then those people after they leave the FDA go to work for those very same manufacturers? Are you aware there are people that are concerned about that?
MS. KABBASH: Objection.
THE WITNESS: I've never spoken to any person like that, but I can't -- I imagine there may be some people like that.

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BY MR. SLATER:
Q. It's a legitimate concern, isn't it, that the people who are supposed to be safeguarding the public health for the FDA are interacting with large medical device and prescription drug manufacturers, making decisions that impact on the public health, and then turn around when they leave the FDA and go to work for these very same manufacturers? That -- you can understand that people would be concerned about that. Right?
MS. KABBASH: Objection.
THE WITNESS: Well, the Congress in its wisdom has identified statute. FDA's created regulations to control post-employment of people who worked at FDA; and as long as you comply with those requirements, then you can do what -- whatever consulting you want to do.
BY MR. SLATER:
Q. Well, you understand that there's some people who think that those protections are not substantial enough and that the public safety is being jeopardized by the fact that people can leave the FDA and go to work for the very companies that are submitting these drugs and devices for review to the FDA.

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MS. KABBASH: Objection.
THE WITNESS: Well, that's fine. I'd say, first of all, talk to the Congress because they created the ability for people to do that.
And, secondly, who better is able to provide information to manufacturers on how to work your way through the process in order to obtain approval for devices?
80-some or more percent of device manufacturers are small manufacturers, 50 or fewer employees, and they don't have a clue how to get a product to market.
BY MR. SLATER:
Q. Wouldn't the best person or entity for those companies to ask for help -- wouldn't the best source of information be the FDA itself?
A. There -- there are resources for small manufacturers, but FDA's not there as a consultant. They take you only as far as they can and then rely upon consultants and others to help the companies along.
Q. There's something known as a Regulatory Affairs professional. There are some of the people like that who work in Ethicon who never worked for the FDA. You're not telling me that the

only people who can understand the process are people who used to work in the FDA, are you?
A. No, I'm not saying that. Everyone brings their particular expertise, backgrounds to the table to help expedite products to the marketplace.
Q. If one or more of the labels for these devices was false or misleading in any particular, that would be misbranding; correct?
A. If that was the final decision by assessment of the facts, yes, that would be a misbranding. That's what misbranding is, in part.
Q. The final -- well, rephrase. Do you know -- well, rephrase.
It was Regulatory Affairs that had the ultimate decision making as to whether or not the disclosure of risks with the Prolift and Prolift+M was sufficient in the IFU, for example; correct?
A. While I think Medical Affairs had provided input, who the responsible party for the IFU generally probably was Regulatory Affairs, as it is in most companies, but they do not act alone in regard to the content of IFUs.
Q. Regulatory Affairs relied heavily on

Medical Affairs at Ethicon in deciding what risks and other important information was provided to doctors and patients in the labeling for the Prolift and Prolift+M; correct?
A. That's my understanding, yes.
Q. Therefore, if Medical Affairs failed to disclose to Regulatory Affairs important medical risks such that they did not get into the labeling, that is a failing by Medical Affairs which could have significant impact on patients; correct?
A. Well, the only thing Regulatory Affairs knows is what they know. Regulatory Affairs does rely on Medical Affairs, and what Regulatory Affairs usually does -- what people usually do is also look at predicate labeling, other products, to get a sense of IFUs for similar products.
So they rely upon Medical Affairs primarily, but it's not their only source of information.
Q. With regard to the Prolift and Prolift+M, Regulatory Affairs relied heavily on Medical Affairs for medical information so that determinations could be made as to what would be disclosed in the labeling; correct?
A. I've seen deposition testimony to

that effect, yes. "Heavily," I guess, is a -- you know, interpretable.
Q. You're familiar with the 522 orders that were provided to Ethicon by the FDA; correct?
A. Yes.
Q. Those were issued on January 3, 2012; correct?
A. Thereabouts. I don't recall the exact date. I have to look at my report, but thereabouts.
MS. KABBASH: Wait. I'm sorry. Adam, what date did you just say? Can you read back what he just said?
MR. SLATER: I thought I said January 3, 2012.
THE COURT REPORTER: (Court reporter nods head.)
MS. KABBASH: He did? Okay. Sorry. I misheard you. Go ahead.
MR. SLATER: I may have said the wrong date. If I did, let me know.
BY MR. SLATER:
Q. The 522 orders issued by the FDA are important statements by the FDA that the FDA had concern about the safety and effectiveness of the

devices that those orders covered; correct?
A. Well, the genesis resides -- the foundation for the letters is an underlying concern, yes, but whether or not that concern is borne out depends on the results of the study.
Q. The 522 studies that were ordered with regard to the Prolift and Prolift+M were never performed; correct?
A. That's correct.
Q. Do you know how soon after the 522 orders were issued there was internal discussion within Ethicon about whether or not they could avoid doing the 522 studies by withdrawing the Prolift and Prolift+M from the market?
A. I don't recall -- it may be in my report, references to some e-mails or something, but there was discussion of the impact of the 522 orders, yes.
Q. As you sit here now, do you know how soon after the 522 orders were issued it was that Ethicon internally began to discuss the possibility of avoiding the 522 studies by withdrawing the Prolift and Prolift+M from the market?
A. I don't know exactly. I don't know if my report talks about that specifically. I could

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turn to it, but I don't recall specifically.
Q. Do you have any information as to why it was that Ethicon changed the indications for Gynemesh PS to indicate that it should only be placed abdominally and no longer should be placed through the vagina?
MS. KABBASH: Objection.
THE WITNESS: I seem to recall that was the case. I don't recall the wherewithal or the foundation for that.
BY MR. SLATER:
Q. You certainly offered no opinions with regard to that subject; correct?
A. I don't believe so.
Q. You certainly don't hold any opinions with regard to what the results would have been if the 522 studies had actually been performed for the devices; correct?
A. No, I don't, nor -- I'm not sure how I could in any -- or anyone could, for that matter, talk about those.
Q. You don't hold any opinion on that subject; correct?
A. No, I do not.
Q. When Ethicon was granted 510(k)

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clearance for the Prolift, was that clearance contingent on Ethicon issuing a revised IFU and a patient brochure in compliance with the dialogue that had occurred prior to clearance?
A. Part of the process was -- were changes to the IFU. Ethicon already had some stuff in the IFU that FDA had requested, but Ethicon had to amend the IFU and the patient brochure, yes. That's part of the FDA's expectation as far as the clearance is concerned, the formal clearance.
Q. The review of the Prolift and Prolift+M that actually took place as part of the 510(k) process was not as robust or detailed as what information would have been generated if the -- if a premarket approval process had taken place; correct?
A. Could you repeat the question?
Q. Sure.
The process that took place with the 510(k) for the Prolift and Prolift+M, the review by the FDA was not as robust or detailed or extensive as what would have occurred if it had been a PMA, a premarket approval, process; correct?
A. Well, there's some elements of the PMA process that aren't involved in the 510(k) process; but as far as the rigor of

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scientific/medical review, I think it was probably, in my estimation, based upon my review of the documents, I think every bit as robust as a PMA review.
Q. What elements were not included in the 510(k) process that would have been part of a PMA?
A. Well, one thing, there's a review by a panel of all PMAs, virtually all PMAs. That occurs after FDA's substantive review, so FDA's -- of a PMA.
So FDA's substantive review of a PMA takes about -- takes about 90 days, 80, 90 days -- not totally 90 days, but the timeframe is the same timeframe as a 510(k). So FDA's reviews both ways are virtually equivalent, PMA/510(k).
Now, there's some more information in a PMA that's submitted than a 510(k), increases the PMA review time a little bit, all the manufacturing information, for example.
PMA may include prospective clinical studies that 510(k)s may not include. This submission had reference to clinical data which was evaluated.
So I think for a 510(k), this is --

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this is a pretty thorough, robust 510(k) and review process.
Q. Okay. Here's my question. It's very simple: If a PMA process had been followed for the Prolift and Prolift+M, additional information would have been reviewed and additional steps would have been taken; correct?
A. Yes.
Q. One of the additional steps would have been review by a panel; correct?
A. Yes.
Q. More information would have been included in the PMA application than was included in the 510(k); correct?
A. Yes, such as the manufacturing volume that's submitted.
Q. There would have been additional information with regard to clinical studies as part of a PMA process as compared to a 510(k); correct?
A. There's typically need for clinical data in a PMA. In many cases, it's prospective clinical trials. In some cases, it's published studies with the device from foreign locations or other clinical information.
Q. Ethicon as part of the 510(k) process

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gave some clinical data to the FDA regarding the Prolift; correct?
A. Yes.
Q. If that data was false or misleading in any way, that would be highly inappropriate; correct?
A. "False or misleading in any way." I -- it would have to be material, I think. We get back to that issue of materiality.
Q. Okay.
If any of the clinical data that Ethicon provided the FDA as part of the 510(k) process was materially false or materially misleading, that would be highly inappropriate; correct?
A. Yes, subject to a medical opinion, I think, or statistical opinion, whatever expertise needs to come to bear to determine materiality. Not my purview, but just saying what you'd need to establish materiality.
Q. If the clinical data provided by Ethicon to the FDA as part of the 510(k) process was materially misleading or materially false from the standpoint of either medical expertise or statistical expertise, objectively viewed, that

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would be highly inappropriate; correct?
A. If that's the finding by FDA, upon becoming aware of that information, that it was material. But, you know, that would be the decision -- sometimes information that's omitted and later becomes known, FDA has not considered it to be material themselves.
Q. You, sitting here as an expert in this case, would agree with me that if objectively viewed, from a medical or a statistical viewpoint, the clinical data provided by Ethicon to the FDA was materially misleading or materially false in any way, that would be highly inappropriate; you would give that opinion right now; correct?
A. Well, I -- I guess me, I wouldn't be evaluating the materiality from a statistical or medical point of view. If I were the Director of Compliance and it was the opinion of the Office of Device Evaluation that, in their view, this information was material to the PMA finding, I'd have a -- I would think -- yes, I would -- I would think that would be important and a problem.
So who's making that decision, who's the responsible party for making that determination and, you know, is it material.

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Q. I would like you to assume that information provided by Ethicon to the FDA as part -- rephrase.
I would like you to assume that clinical data provided by Ethicon to the FDA was materially misleading and materially false in certain significant respects. I'd like you to assume that, that whatever -- however you design those terms, it would meet all of those definitions.
You would agree with me as an expert in this case that that would be highly inappropriate; correct?
A. Based on your assumptions and FDA's conclusions that -- by the responsible parties at FDA that it was material, then that would be a problem.
Q. It would be highly inappropriate; correct?
A. If it -- yes, if it was material in their final conclusions.
Q. If Ethicon provided clinical data -- well, rephrase.
We know that Ethicon provided some clinical data to the FDA regarding the Prolift and Prolift+M.

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If Ethicon had additional clinical data that it knew would cast serious doubt on the safety and/or effectiveness of the Prolift and failed to provide that information to the FDA, that would be highly inappropriate; correct?
MS. KABBASH: Objection.
THE WITNESS: I don't know. That gets again to the point of materiality and a medical sort of opinion.
BY MR. SLATER:
Q. And if it meets that definition in my hypothetical, you would agree that would be highly inappropriate; correct?
A. If FDA's --
MS. KABBASH: Objection.
THE WITNESS: -- conclusion is it was material and important and all the provisos you've provided, I think that would be an issue.
BY MR. SLATER:
Q. Do you have any information as to when the new Prolift patient brochure actually went into use, not when it was copy approved, but when it actually began to be provided to physicians and patients after 510(k) clearance?
A. I think, in my report, I talk about

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that episode and have an opinion on that, so --
Q. I'm talking about the patient brochure here --
A. The patient brochure, is that what you said?
Q. Yes. Do you know when it actually began to be provided to physicians and patients after 510(k) clearance, the new one, the one that was changed after the clearance process?
A. Yeah, sorry. I was thinking about the IFU. Patient brochure, I'm thinking four to six months afterwards.
Q. Here's my question -- we know the copy approval date. That's not what I'm asking you for, though -- I'm asking, do you know when it actually went into circulation, when Ethicon actually started providing it to physicians and patients?
A. The only thing that comes to mind is four- to six-month timeframe for getting the brochures out. I don't know when it hit the streets. I thought that was the timeframe.
Q. What do you base your assumption on?
A. The documents I've reviewed, testimony, as far as I recall.

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Q. Let me tell you why I'm asking the question. I've been asking a lot of questions in this case of a lot of other people and trying to find out when the patient brochure, the revised patient brochure, actually began to be used, when it actually got circulated to patients and physicians, and no one's been able to tell me.
I've been told by the company the best they can tell me is, it was copy approved in October of 2008, but nobody knows when it actually started to get used.
I'm asking you, do you have any information beyond that to tell me when it actually went into use?
A. Well, actually, I think what I'm thinking of is, I don't think Prolift+M hit the streets until the following year.
Q. I'm asking about the Prolift patient brochure.
A. Okay. The Prolift patient brochure, I can't say with certainty. I know when -- Prolift+M took some time before it was actually marketed. It was the following year when it actually was marketed, was launched, so to speak.
As far as when the Prolift brochure,

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I don't know.
Q. Okay.
So just to be clear, with regard to my question with regard to the Prolift brochure, you don't know; correct?
A. No, I don't know specifically.
Q. Do you know what patient brochure was used with the Prolift+M when it began to be marketed?
A. What specific edition, version --
Q. Yes.
A. -- is that what you're asking me?
Q. Yes.
A. I don't recall. I had a listing of -- of labels and edition dates at one time. I just don't recall what version --
Q. Do you know which Prolift -- I'm sorry. Do you know which IFU was used with the Prolift+M when it was put on the market?
A. I can't speak to you about specific versions, whatnot. I'd have to look at a couple records that were provided to me, if that's revealing, in regard to the version and the dates of distribution.
Q. One of the items listed on your list

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of materials is Prolift+M IFU, Plaintiffs' Exhibit 14. Now, that is on the -- I think the fifth page of your materials list -- it is. It's at the top of the fifth page, second item.
A. And that's Exhibit --
Q. Exhibit 7.
A. 7.
Q. 7.
A. And the top of page -- I don't think there's numbers on them.
Q. It's about the sixth page in?
A. Okay.
Q. I counted the pages.
A. Okay. And you're referring to what now?
Q. The second item on the -- well, rephrase. In Exhibit 7, the second item on the sixth page, it says 5/15 Prolift+M IFU, Plaintiffs' Exhibit 14. Do you see that?
Second item on the page?
A. Yeah, hang on a second. Two, three, four, five, page six -- the second item.
Q. You know what? It's the fifth page. I apologize.
A. Okay. Okay. I'm with you now. Yes,

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I see that.
Q. Okay.
Here on the fifth page of Exhibit 7 at the top, the second item, it says, 5/15, that's 5/15, Prolift+M IFU, Plaintiffs' Exhibit 14.
First of all, what's the 5/15 mean?
A. I'd have to look at Exhibit 14. Maybe the date of that exhibit. I'm not sure offhand.
Q. I have the document in front of me and it has a date of June 11, 2008 in the bottom-right corner so -- you can't tell me what the 5/15 means?
A. It may have been a date when I was provided the document. I can't say with certainty.
Q. And this Prolift+M IFU, was this a document that was of significance to you, the document listed here on this list?
A. I'm sure I considered it in regard to my report.
Q. And did you assume this was the form of the Prolift+M IFU that was used with the Prolift+M when it went on the market?
A. I don't recall. I'd have to see if I -- how and where I referenced this exhibit.

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Q. It's the only Prolift+M IFU listed on what you reviewed, so this would be the only one you looked at. Right?
A. Well, it may be -- there may be other IFUs in exhibits, depositions, so I can't say it's necessarily the only IFU I saw.
Q. As you sit here now, can you tell me if you saw any other Prolift+M IFU?
A. Oh, I'm sure I've seen others, probably in exhibits.
Q. Which ones?
A. Oh, I can't say with certainty.
MS. KABBASH: Hey, Adam, our videographer says that we have five minutes left on the tape. Can we plan to take a lunch at that point in time?
MR. SLATER: Sure. I'll ask just a couple more minutes of questions and then...
BY MR. SLATER:
Q. If you go back a couple of pages to the third page of this exhibit, your list of materials, about two-thirds of the way down the page, it says, the Prolift IFU --
A. Okay.
Q. -- and then some Bates numbers?

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A. Yes.
Q. Why did you list that IFU?
A. It probably was provided to me as a separate document along the way.
Q. Did you assume that was the IFU that was actually in use for some period of time?
A. I'd have to see how and where I referenced it in my report.
Q. Did Ethicon make any effort to your knowledge to tell physicians and patients that the Prolift IFU and patient brochure that was in effect as of May 15, 2008 were both going to be changed in material respects?
A. I don't think I've seen records to that effect.
Q. So, therefore, after May 15, 2008, doctors and patients were still being provided and relying on the Prolift IFU and patient brochure that the FDA had told Ethicon they needed to change in certain material respects; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, whatever was being provided was -- was the document that was being provided, so if -- you know, that's what you're asking, I think.

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MR. SLATER: Why don't we break for lunch now.
MS. KABBASH: Okay.
MR. SLATER: And how long do you guys -- let's get off the video first. Then we can talk.
THE VIDEO TECHNICIAN: The time now is 1:26. We are going off the record. This is the end of disc number one.
- - -
(A discussion off the record occurred.)
- - -
(A luncheon recess was taken from 1:28 p.m. to 2:23 p.m.)
THE VIDEO TECHNICIAN: The time now is 2:23. We are back on the record. This is the beginning of disc number two.
BY MR. SLATER:
Q. Mr. Utalowski, on the second page of Exhibit 7, you have a section that says "Other." And right under that, you say you looked at the 510(k) notification for Prolene hernia repair mesh and the FDA clearance letter for Prolene mesh.
Do you see that?
A. Yes. Yes.

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Q. Were those documents of any particular significance to you in forming your opinions in this case?
A. Other than being background for the development of the Prolift, of course, they're important there, but other than that, no.
Q. Okay.
You ultimately do not have any opinions as to whether or not the labeling for the Prolift and Prolift+M was adequate or not; correct?
In the sense of whether or not risks and other information that needed to be included was included, you're not forming opinions on that question. Right?
A. I think generally I do have an opinion regarding labeling in terms of meeting regulatory requirements generally. As far as any specific element that requires a medical assessment, no.
Q. So your opinion essentially is, Ethicon had labeling as required, but you're not forming an opinion as to the actual completeness of the warnings or accuracy of the warnings or anything of that nature which would require medical expertise; correct?

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A. With that last part of what you said, yes.
MR. SLATER: Just so you know, I'm flipping through some of my notes and trying to cut through some of the questions I might have had to ask.
MS. KABBASH: Okay.
BY MR. SLATER:
Q. Okay.
Would you agree with me that if a serious adverse event was disclosed to Ethicon, for example, a doctor told somebody in the Marketing Department that he was treating a patient with a significant Prolift complication, that that information needed to be passed on to the FDA by Ethicon?
A. Well, first of all, it has aspects of whether -- first of all, it's a complaint and whether the complaint is reportable to FDA, if that's the point of your question.
Q. Well, take, for example, the following hypothetical scenario: A doctor tells a marketing executive with a title of product director at Ethicon that he is treating a patient who has a severe adverse event due to a Prolift and that the

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patient has suffered severe injury as a result.
Under that circumstance, Ethicon is required by FDA regulations to get that information to the FDA; correct?
MS. KABBASH: Objection.
THE WITNESS: Not -- not completely. First of all, I believe that -- and who is the person at Ethicon you just mentioned was in that conversation?
MR. SLATER: A product -- it's a product director in the Marketing Department.
THE WITNESS: Okay.
MR. SLATER: Overseeing the Prolift.
THE WITNESS: I understand. Well, I think that interaction would have to be controlled as a complaint, first of all, in Ethicon's complaint system.
And then that complaint would have to be evaluated and investigated to obtain more information on that complaint, to document the circumstances, and then a decision rendered whether that complaint was a reportable event as a medical device report to FDA.
BY MR. SLATER:
Q. Tell me if I understand correctly.

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If a doctor reported a serious adverse event that resulted from a Prolift to a marketing executive with the title of product director within Ethicon, that -- that would have to be addressed as a complaint in the internal complaint system within Ethicon; it would have to be investigated, and then a decision would have to be made whether this was reportable to the FDA; correct?
A. That's correct.
Q. And the decision as to whether or not it would be reportable, what would be the criteria?
A. The criteria are, is it -- does it meet the -- the definition of a serious injury according to the MDR regulation. Relatedness has an aspect, as long as it may be related, then that criterion is met; and any interventions that were taken; any outcomes of the patient would be a determining factor whether it was reportable.
Any aspect of a malfunction related to the device would be another aspect related to the reportability.
Q. In deciding whether or not a complaint is reportable, the medical device manufacturer has to determine, first, is this a serious injury per the MDL regulation; two, does it

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meet the criteria of, quote, unquote, it may be related to the Prolift -- in this case, that's the device -- three, were any interventions undertaken and what were the outcomes; and then, four, is there any aspect of a malfunction implicated.

Those would be the criteria for whether or not it's reportable; correct?

A. Yes. Primarily, yes.

Q. In my hypothetical scenario, if -- well, rephrase. Let me ask a different question.

What's the criteria for whether or not something is a serious injury under the MDR reg?

A. Well, what is a -- what is a serious injury is defined in the regulation, basically affecting structure or function, permanent impairment, an event requiring intervention to prevent a permanent impairment.

Q. If, in my hypothetical scenario, surgery had to be performed on this woman to attempt to treat the injuries that she suffered due to the complications from the Prolift, this would qualify as a serious injury requiring report; correct?

A. Well, in terms of that aspect of it, that certainly is an intervention, I agree with you there.

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Q. And if an objective view -- if an objective observer looked at this and said it, quote, unquote, may be related to the Prolift, this would need to be reported to the FDA; correct?

A. Yes, I think that speaks to a reportable event.

Q. You said something earlier. You said if there's any aspect of a malfunction, that would be something to look at. Is a malfunction defined, in simple terms, as the failure to operate or perform as intended?

A. That's basically it. It -- does it perform as intended, does it meet its specifications, yes.

Q. The Prolift is not intended to erode through the vaginal wall into the vagina, is it?

MS. KABBASH: Objection.

THE WITNESS: We're talking about intended use, and that is, does it serve as a support -- organ support in terms of pelvic organ prolapse.

Now, there are adverse events that are attendant to the product, so specifications, problems would be, did it tear, did it fail in some form, in some untoward means.

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Erosion, I don't know if that would be a malfunction, per se.

BY MR. SLATER:

Q. The Prolift is intended to provide support for prolapsed pelvic organs; correct?

A. Yes, correct.

Q. If after the placement of a Prolift a recurrence happens and the woman's prolapse returns, that would be the failure of the device to operate as intended; correct?

MS. KABBASH: Objection.

THE WITNESS: I think that would have to be evaluated to determine the causation, so some medical opinion, medical assessment of that.

It could have -- the failure could be caused by issues not related to the -- to the mesh. It could be -- well, I don't even want to speculate. That's a medical assessment.

BY MR. SLATER:

Q. If a recurrence of prolapse were to result from something inherent to the mesh itself, for example, that due to scar tissue formation, there was contraction of the mesh, which led to inadequate coverage of the defect and thus a re-prolapse occurred, that would be a failure of the

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Prolift to perform as intended; correct?

A. Well, one thing that has to be connected to the malfunction is serious injury, again, or the potential for serious injury, so it has --

Q. I'm not asking about reportability here.

A. No --

Q. Wait. I'm not asking about reportability here. I'm just asking the definition of malfunction.

A. Yes, and I'm getting to that point. The definition of malfunction has an element of serious injury or death, the probability of serious injury or death, a connection to serious injury or death. A malfunction is not reportable otherwise.

So the point I was going to make --

Q. I'm not asking you about reportability, though.

A. I understand you're talking about malfunction -- oh, okay.

Q. So why do you -- so then here's my point. Let me try to get this cleaned up.

As I just posed that question to you a moment ago, that would be a malfunction of the

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Prolift; correct?
A. Well, and the point I'm making is, are we talking about malfunction as defined in the medical device report -- reporting regulation? Because in that regulation, malfunction is defined as well, and malfunction is defined also in connection to serious injury or death related to the malfunction.
So it's -- it's -- there's a connection there.
Q. So is malfunction defined in different ways under different circumstances, for example, whether or not you're considering reportability?
A. Yeah, there has to be potential for death or serious injury should the malfunction recur, so you have to have some assessment, some connection, to a, for example, serious injury related to that episode.
Q. For the malfunction to be reportable.
A. That's correct.
Q. Is there another definition of a malfunction that does not include the serious injury or death language, where you're just tying to define whether or not a malfunction occurred?

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A. Oh --
Q. Let me ask it differently. You can have a malfunction without, quote, unquote, serious injury or death; correct?
A. Yes.
Q. The question of whether or not the malfunction needs to be reported, you'd have to determine whether there was serious injury or death or the potential for serious injury or death; correct?
A. Correct.
Q. So in the example I gave you a few moments ago, just in terms of whether or not a malfunction occurred, that would be a malfunction; correct?
A. What was your example again? Let's go back to that.
Q. Okay.
I gave you an example a moment ago of a recurrence that occurred where there was contraction of the mesh which led to inadequate coverage of the defect -- let me rephrase it.
I gave you the example -- one second.
(Pause.)
BY MR. SLATER:

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Q. I gave you the example a moment ago of contraction of the Prolift mesh leading to a lack of coverage of the prolapsed organ -- the organ that had been prolapsed before, leading to a recurrence of the prolapse.
If that were to occur, that would meet the definition of a malfunction; correct?
A. Well, you're saying the definition of a malfunction. What definition are we using now? It would meet the --
Q. The product did not perform as intended.
A. It would meet the definition of malfunction under the medical device reporting. I'm also thinking of the quality system regulation as a -- there's probably some aspect of malfunction there related -- or lack of performance as intended.
But -- but generally -- is it a malfunction? You know, I don't know. That might require a medical assessment, I think, whether that really is a malfunction of the device or -- or some other characteristic of how the device performs in the body. I just can't say.
Q. No opinion one way or the other.
A. No, no, I think that incurs some

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medical assessment in my mind.
Q. In the definition of a reportable malfunction, there's the term serious injury or death whether it actually occurred or potentially could occur.
How -- is serious injury defined -- how is that defined --
A. I think we went over --
Q. -- in that context?
A. Well, I think we went over that. There's only one definition of serious injury in the medical device reporting regulation.
Q. Okay. It's the definition you gave me a few moments ago?
A. Yeah, that's permanent impairment, interventions to require -- to -- to prevent permanent impairment.
Q. So if, in fact, a Prolift was put into a woman, contraction of the mesh occurred, and that led to recurrence of prolapse and the patient then needed additional surgery to both remove the contracted mesh and to treat the re-prolapsed organ, that would be a reportable malfunction; correct?
MS. KABBASH: Objection.
THE WITNESS: I -- I think there's

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still that -- I -- I wouldn't want to opine on the malfunction aspect of the retraction, because I think that -- it's my understanding, lay person's understanding, that retraction, tissue ingrowth, is an element of a lot of mesh surgery, so I'd leave that up to the medical people to consider that aspect of it.
BY MR. SLATER:
Q. All right. You won't be forming any opinion on that one way or the other.
A. No.
Q. If a woman had a Prolift put in her body and the Prolift mesh eroded through her vagina and, in addition, as a result of the erosion of the mesh, there was a lack of support for the prolapsed organ and a recurrence of prolapse occurred, would that be a reportable malfunction or do you have no opinion on that?
A. I think that incurs the need for a medical opinion.
Q. What would be the information you would need from a medical standpoint to be able to answer that question?
A. I think you'd have to ask the medical person assessing as far as what he or she would

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need.
Q. Well, what would be the criteria that you would need to have answered to determine whether it's reportable or not? What would you need from the medical people information-wise to be able to answer that question?
A. Well, that it was -- it -- there was a serious injury involved, it was -- it may have been --
Q. I just gave you surgery, so -- I just gave you that this patient had to go through surgery. So we satisfy that element. Right?
A. Well, that's not the whole definition of a serious injury under the medical device reporting regulation. Okay? Serious injury has the element of not only impact. It also has the element of permanence and intervention, so you have to consider all those aspects.
Q. Wait. Are you telling me that if a patient suffers an injury due to a medical device like the Prolift, she undergoes surgery, but in the end of the process doesn't have a, quote, unquote, permanent injury, that's not reportable?
A. Well, the point is, surgery to prevent permanent impairment, so that -- those are

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medical opinions.
Q. Okay. So let's -- so here's what I want -- so I'm learning from you.
So you need to know was there surgery performed to prevent permanent impairment or did permanent impairment -- permanent impairment occur. Those are aspects of information you would need. Right?
A. Yes.
Q. What else would you need to know for whether or not this was a malfunction that needed to be reported?
A. Well, you'd have to have some information related to what is the defect that's in regard to the product, that's related to this event, so that would be both medical and perhaps engineering assessment.
Q. And I've told you now that the mesh -- take an example where the mesh eroded through the vaginal wall into the vagina. So we understand what happened now, so that would lead towards a reportable malfunction; correct?
A. Well, I just -- you're -- you're testing the limits of my medical understanding. I think erosion -- I don't know if FDA would consider

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erosion in the bin of -- and it was -- and there was intervention, whether they'd consider that in the bin of a serious injury or within the bin of a serious injury and a malfunction. I don't know how they would categorize that generally.
Q. Well, you do know that the FDA considers erosion of mesh through the vaginal wall to be a serious injury; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, it -- it's -- by the definition of the medical device reporting regulation -- you may be thinking of the term more generally, but I'm talking about the term as it's defined in the medical device reporting regulation, so in what instance are you --
BY MR. SLATER:
Q. As the term is defined by the -- right, as the term is defined by the FDA, they consider erosion of the mesh through the vaginal wall into the vagina to be a serious injury; or if you want to call it a serious adverse event, either way, the FDA considers it to meet those criteria. Right?
MS. KABBASH: Objection.
THE WITNESS: I'm not so sure about

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that.
BY MR. SLATER:
Q. You don't know.
A. I don't know -- I know that --
Q. That's my question, do you know or not?
A. And I was answering your question. The point is, for example, medical --
Q. No, there's really no example. The question is, do you know the answer or not? It's a "yes" or "no." Do you know whether the FDA considers erosion of the mesh through the vaginal wall into the vagina to be a serious injury or a serious adverse event?
MS. KABBASH: Objection.
THE WITNESS: I don't know.
(Pause.)
THE WITNESS: I mean, that's a standing question, so let me just add that, if there's no intervention and there's spontaneous healing, it's not a serious injury.
If there's cream applied, that's not considered a -- by FDA an intervention, then there's no serious injury. So those are the provisos.
BY MR. SLATER:

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Q. If there is surgery performed to treat this eroding mesh through the vaginal wall, then it is serious. It's a serious injury and it's a serious adverse event; correct?
A. It -- I think it could be, yes.
Q. Well, it actually would be; correct? Not could be, but would be.
A. Well, there's certainly an intervention and was the intervention to deter permanent impairment, I mean, that's a -- we're getting to a medical conclusion.
Q. If the answer to -- if the answer to that is yes, then it's a serious injury and a serious adverse event; correct?
MS. KABBASH: Objection.
THE WITNESS: If that's the opinion of the company and/or the FDA, then it would be.
BY MR. SLATER:
Q. Just so I don't forget, we had been going through the exhibits a little earlier and I -- I want to pick up now with Exhibit 8, if you could. I just want to make sure I cover the last three exhibits before I do some cleanup questions with you.
A. Okay.

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Q. All right. What is Exhibit 8?
A. It looks like the contract on this particular litigation, that being POP mesh.
Q. This was your engagement letter?
A. Yes.
Q. And if I understand correctly from your prior testimony, you are currently reviewing the TVT devices --
A. Yes.
Q. -- and analyzing regulatory issues in connection with those devices?
A. Yes.
Q. The testimony you've provided to me in terms of definitions and process and procedure and how those things would apply to the Prolift in general, that would also apply to the TVT devices; correct?
MS. KABBASH: Objection.
THE WITNESS: Generally, yes.
BY MR. SLATER:
Q. Okay. Let's look at Exhibit 9 now, if you could tell me what Exhibit 9 is, please?
MS. KABBASH: They might be out of order. There you go.
THE WITNESS: 9 is the two-page PDF

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on my prior testimony, deposition and court testimony.
BY MR. SLATER:
Q. On the second page, there's two trials listed. One is the Strum versus DePuy Orthopaedics case. That just happened this -- earlier this year in Illinois; correct?
A. Correct.
Q. And DePuy is the party that you testified for in that case --
A. Yes.
Q. -- correct? And you understand that DePuy is a company that's owned by Johnson & Johnson. Right?
A. Yes.
Q. The second case is Brenda F. Kitrosser versus Nuvasive, Inc. When did that testimony take place?
A. I think last year sometime, if I'm not mistaken.
Q. What's the issue in that case -- sure. What was the issue in that case?
A. I testified as expert for Nuvasive and Nuvasive's product -- they make several products, but product litigation regarding a spinal

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device.
Q. Were you giving labeling opinions in that case?
A. Labeling, 510(k), yes, FDA's process.
Q. Tell me if I understand your overall testimony. I think your overall testimony focuses on whether or not there were processes in place that were followed -- well, rephrase. Let me ask the question differently.
If I understand your overall testimony, it's that certain processes were in place and Ethicon took steps to implement or comply with those processes. That's -- that's your general gist of your testimony in this case; correct?
MS. KABBASH: Objection.
THE WITNESS: No, I have several opinions -- you mean what we talked about today or what?
BY MR. SLATER:
Q. Well, I'm talking about overall -- let me ask it more specifically.
To the extent that you have opinions that there were processes that were in place, ultimately, you're not offering any specific opinions that would rely in any way on medical

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knowledge or medical expertise. That's a true statement; correct?
A. That's correct.
Q. Let me ask you a question about the FDA 510(k) process for the Prolift and Prolift+M.
Ultimately, the FDA made whatever decisions it made based on the information available to it. That's a true statement. Right?
A. You're referring to the 510(k) clearance or what are you referring to?
Q. Yes, 510(k) clearance.
A. It made its decision based upon, as I said before earlier in the day, what's -- as it does for all 510(k)s, it renders a decision based upon what's submitted to it, as well as the information it brings to bear in the particular review process internally, the expertise, the knowledge, the background it has.
Q. You did not offer any opinions to the effect that if there was information that was not provided to the FDA as part of that process, that if that information had been provided, how that would have impacted on the FDA's decision making. You didn't address any questions on that subject; correct?

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A. I don't believe I have an opinion in regard to that.
Q. Okay.
You offered no opinions, if I understand correctly, that if a PMA process had been initiated for the Prolift and Prolift+M, as to what clinical studies the FDA may or may not have required if that occurred, you didn't offer any opinions on that subject; correct?
A. Not directly. I opined regarding the rigor and thoroughness of the 510(k) review.
Q. But you did not offer any opinions one way or another as to what clinical studies the FDA may or may not have required if, in fact, a PMA process had initiated with the Prolift and Prolift+M; correct?
A. Well, I didn't go down that theoretical, hypothetical pathway because it didn't occur.
Q. Okay. So it's not something you opined on; correct?
A. That's correct.
Q. If Ethicon had information in its files which would have indicated that there were new issues of safety and effectiveness for the Prolift

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systems -- I'd like you to assume for this hypothetical that that information existed, but was not provided to the FDA -- you did not offer any opinions with regard to that scenario; correct?
MS. KABBASH: Objection.
THE WITNESS: The only related opinion was in regard to FDA's assessment of the issues in their determination that -- that there were no new issues.
BY MR. SLATER:
Q. You would agree with me Ethicon had far more knowledge about the safety and effectiveness of the Prolift than the FDA did; correct?
A. Well, you used the term "far." I think that companies will have information in its records that go beyond what's submitted to FDA. As far as far more information, I don't know how to characterize -- how to consider that, I guess.
Q. You did not offer any opinions to the effect that if certain information which was not provided to the FDA had been provided -- how the FDA would have ruled if that information was provided, you did not address that type of scenario in your opinions; correct?

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A. No, not directly. I think that, you know, we're -- at the point when the product was cleared, that FDA was making public health notifications and later had a panel meeting where it became aware of or there was discussion of basically all the information on the table regarding meshes. And they didn't take any regulatory action against any of the meshes, except for the 522 orders, ultimately.

So it's an indicator that whatever additional information Ethicon had or the industry generally had, it didn't impact the regulatory status of the meshes, per se, as far as their ability to be marketed.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. You did not offer any specific opinions with regard to any particular information -- for example, information that Dr. Weber raised in her report and said, look, this is information that was not provided to the FDA that I think was material.

You didn't address anything like that and say, well, in my opinion, it wouldn't have had an impact; you didn't offer such an opinion;

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correct?

A. Well, let me go through my opinions for a moment just to make sure, to be precise.

(Pause.)

THE WITNESS: Well, in FDA's review of the 510(k), I think that several of Dr. Weber's points were brought up by FDA even during their review.

And I think with the rest, as far as FDA's conclusions were concerned -- for example, FDA themselves raised the issue of, this looks to us like a complex procedure, this looks to us like you need specific training, this looks to us like this and that.

So FDA themselves were raising points that Dr. Weber raised; and with their eyes wide open and in view of what Ethicon provided, they decided to clear the product.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Now, if you could, please, because I'm really trying to wrap this up with you, but I'll go until, you know, midnight if I have to with you, I'd just like you to focus on my question: You did not offer any opinions with regard to what the FDA

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would or would not have done if additional information that was in FDA -- in Ethicon's files with regard to safety and effectiveness, but that was not provided to the FDA, had been provided; that's just not something you addressed; correct?

A. Well, I guess we'd have to get specific about that. I mean, what issues, for example?

Q. Well, how about any; you offered no opinion on that subject; correct?

A. I offered an opinion that there were no new issues of safety and effectiveness and FDA --

Q. Well, you said that that's what the FDA decided, but you didn't offer the opinion there was no issues of safety and effectiveness because you're not qualified to offer that opinion; correct?

A. Well, I --

Q. That's a medical opinion. Right?

A. Well, I assessed what FDA evaluated, what information was provided, how they assessed that; and I think some plaintiffs' expert or experts opined that there were new issues. Well, FDA's making a determination there are no new issues.

Q. Well, you know what, Mr. Utalowski? You know very well that the FDA didn't have all the

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information available to it that Ethicon had available with regard to safety and effectiveness. You know that. Right?

A. I think I've already stated that a company doesn't drive the truck up to FDA with all its files and dump them off at FDA. They have to be selective and judicious, as I mentioned, in regard to what --

Q. Well, selective and judicious does not include -- hang on.

Selective and judicious does not include withholding material information, does it?

A. Well, we already talked about that kind of ad nauseam, yeah, what is material --

Q. Well, I'm sorry if I'm boring you, but I'm going to continue my deposition --

MS. KABBASH: Move to strike.

MR. SLATER: -- ad nauseam.

THE WITNESS: We've talked about materiality. We've talked about in whose opinion is it material. So, you know, what is material?

BY MR. SLATER:

Q. If in fact -- well, rephrase.

The bottom line is, there's no opinion you've ever drawn, and it's not an opinion

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you're drawing now, that if a specific piece of information that was not provided to the FDA as part of the 510(k) process had been provided, how that would have or would not have impacted the FDA's decision on 510(k). That's not something you've addressed; correct?
A. I don't have a specific opinion that goes into that degree of detail, if that's what you're asking.
Q. That's what I'm asking.
A. I have a general opinion that FDA asked questions about new types of issues that Dr. Weber and others raised that FDA also raised and put to rest.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. With regard to my question, you have no opinions on that specific question; correct?
A. No, I just opine that FDA found no new issues.
MR. SLATER: Move to strike after "No."
BY MR. SLATER:
Q. The FDA's decision as to whether there were new issues of safety and effectiveness

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could have been -- I'm not asking you whether it would have or not, but it could have been impacted if additional information had been provided by Ethicon on that subject.
You don't know one way or the other, but it's theoretically possible. Right?
MS. KABBASH: Objection; calls for speculation.
THE WITNESS: I can't say. I -- you know, part of that's a medical/engineering assessment, I suppose.
BY MR. SLATER:
Q. Not something you're opining on; correct?
A. Not engineering or medical/technical aspects, no.
Q. If Ethicon -- well, rephrase.
If new issues of safety and effectiveness existed with the Prolift as compared to Gynemesh PS, then a PMA would have been required; correct?
A. If -- I think this answers your question. If -- the answer is yes. Short answer is yes. If new issues -- if there are new types of issues and that's the conclusion of FDA, then you're

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not equivalent.
Q. And if it's a matter of fact -- well, rephrase. I'll ask you a hypothetical.
I'd like you to assume that when one compares Gynemesh PS, as it was marketed at the time the Prolift 510(k) process took place, and you compare that to the Prolift and Prolift+M in terms of how that was ultimately marketed, if there were new issues of safety and effectiveness with regard to the Prolift and Prolift+M as compared to Gynemesh PS, if that was the fact, a PMA was required; correct?
A. If that was the conclusion of FDA, then a -- it would -- the 510(k) will be not equivalent, then the company had their options.
Q. Well, based on the standards and the regulations, if that was the fact, then a PMA would be required; correct?
A. Well, a company can try and remedy the finding by FDA. They can submit a reclassification petition. There's a couple of options. They can appeal the decision.
So there's several options --
Q. This is what I'm asking you: Objectively, if my hypothetical is correct and there

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were new issues of safety and effectiveness with regard to the Prolift and Prolift+M versus Gynemesh PS, if that was the fact, objectively speaking, applying the regulations, a new -- a PMA would be required; correct?
A. Maybe we're on the same page. What I'm saying is, yes, if FDA -- let me say, if FDA makes the determination that there's new types of questions with the new product compared to the predicate or predicates, then you're not equivalent, the product is not equivalent. That's the FDA's --
Q. You keep saying if the F --
A. That's the FDA's determination.
Q. You keep saying if the FDA decides this -- you keep saying if FDA decides this. I'm not asking you that question. You -- I'm speaking to you as the expert Ethicon's put up in this case. If.
My hypothetical is accurate, by virtue of the regulations, that would require a PMA for the Prolift and Prolift+M; correct?
A. Well, FDA's the final arbiter here. People may think there's new --
Q. Well, I'm asking you as the expert -- but I'm asking you as the expert or are you saying

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you don't have an opinion one way or the other?
A. Well, some of the aspects require medical/engineering assessment. For example --
Q. Wait. Hang on. I don't want examples. Hang on. I don't want examples.
If, based on all the medical assessments, there were new issues of safety and effectiveness for the Prolift and Prolift+M versus Gynemesh PS, if that was the fact, then you can tell me as the expert for Ethicon that, based on the FDA's regulations, a PMA would have been required for Prolift and Prolift+M; correct?
MS. KABBASH: Objection.
THE WITNESS: I guess we're going to agree to disagree, because that's FDA's determination in the final --
BY MR. SLATER:
Q. So you can't form the opinion one way or the other.
MS. KABBASH: Objection.
THE WITNESS: Well, I can tell you that FDA raised issues about potential new issues and put them to rest.
MR. SLATER: Move to strike.
BY MR. SLATER:

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Q. Can you answer my question? Or can't you answer my question?
A. Your question as posed is -- is not appropriate in the regulatory sense, because it's not for me to determine --
Q. Well, I don't think you understand -- I don't think you understand. I'm questioning you as an expert.
You've put yourself up as an expert in this litigation and said, here, I am Mr. Utalowski. I'm an expert on the FDA regulatory process.
So you're supposed to be competent to understand what the regulations would require, so under that circumstance, you should be able to answer this question with a simple "yes" or "no."
If, based on medical assessment, it was proven that there were new issues of safety and effectiveness for the Prolift and Prolift+M versus Gynemesh PS as those devices were marketed, a PMA would be required; correct?
MS. KABBASH: Objection and move to strike statement of counsel.
THE WITNESS: And whose medical opinion are we using here?

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MR. SLATER: A medical opinion that is objectively accurate. Part of my hypothetical, it's a credible, objective medical opinion.
THE WITNESS: People may opine that there's new issues. The ultimate arbiter is FDA.
BY MR. SLATER:
Q. Well, if, in fact, there were new issues, the regulations would require the filing of a PMA; correct?
A. Well, your point is, if, in fact, there were new issues. That's for FDA's final determination as the final arbiter.
Q. And you're not able to say to me that if new issues were shown, that a PMA would be required based on what the regulations say?
A. If FDA identified new issues -- and that's part of the decision process, the regulatory decision process -- they make that determination --
Q. So you can't answer the question.
MS. KABBASH: Objection.
MR. SLATER: So you can't answer the question.
MS. KABBASH: Objection.
MR. SLATER: You don't have an opinion one way or the other. Is that what you're

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telling me?
MS. KABBASH: Objection.
MR. SLATER: You'd have to know what the FDA was going to do in order to answer that question; is that what you're telling me?
THE WITNESS: Well, I observed that FDA raised questions about potential new issues and put them to rest.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. You keep saying that. I keep striking it because it's completely nonresponsive. I don't appreciate it. Please endeavor to answer my questions directly. It will -- everything will go much more smoothly and we'll get done soon, so I'm going to ask my question one more time in hope that at this point we can break the logjam.
Take my hypothetical. If you were satisfied as the expert in this case that from a medical standpoint, there were new issues of safety and effectiveness for the Prolift and Prolift+M as compared to Gynemesh PS, if you were satisfied of that, you would say, as an expert on the FDA regulations, that the regulations would require a PMA; correct?

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A. If I had opined -- assessed the information and opined that there were new issues, in my report, if I opined that, that I believed there were new issues, then I would probably indicate that perhaps FDA would have found the product not equivalent, which they didn't do.

MR. SLATER: Move to strike.

I'm sorry, but is there a reason why you won't just give me a direct answer to the question? Because I'm, actually, with all due respect, getting kind of tired of this.

And I'll tell you why: Because you keep telling me what decision FDA made and you understand one of the claims in this case, if it ever comes up, if you're -- if Ethicon ever tries to parade the clearance out, is to point out to the jury all the important information Ethicon hid behind its doors and didn't tell the FDA about how dangerous they knew the Prolift was. Okay? So you know that that's part of the case.

And you keep parading, though, despite that, that the FDA didn't think there were big -- any issues, when you know for a fact that my position is that they didn't tell the FDA the truth and they withheld a lot of really important

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information.

So please stop going back to what the FDA did on what I am going to prove to the jury, if put in the position of having to prove it, was a false presentation and what I would call fraudulent presentation to the FDA. Okay?

So let's -- that's why I keep striking your answer, so please stop telling me what you wrote in your report.

We're going to try it one more time. I'm going to ask the question again.

BY MR. SLATER:

Q. If you as the -- you call -- rephrase.

You, if you were satisfied, based on medical evidence, that there were new issues of safety and effectiveness for the Prolift and Prolift+M as compared to Gynemesh PS, you would tell me as an expert that, under the FDA regulation, a PMA would be required; correct?

A. Well, first of all, based upon medical evidence, I'm not a clinician, so I wouldn't be in a position to assess medical evidence to render a decision that there's a new issue.

Q. If somebody that -- if you --

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rephrase.

If as a matter of -- I'm going to ask you the hypothetical differently: If as a matter of fact there were new issues of safety and effectiveness for the Prolift and Prolift+M versus Gynemesh PS -- I'm asking you to assume that fact -- you would tell me as an expert, if that's the fact, the accepted fact, then the FDA regulations would have required a PMA for Prolift and Prolift+M; correct?

A. I -- I'll take it as far as, I may consider there to be new issues. But, I mean, the regulations clearly indicate that that's FDA's determination, not mine, not Dr. Weber's, or anyone's, to determine what they consider to be new types of issues, and only FDA makes that decision, so -- and they did not decide that.

Q. So that's not an opinion -- oh, my gosh. Move to strike.

That's not an issue you're going to offer an opinion on one way or the other; correct?

A. No, only to the effect that FDA made the determination there were no new types of issues, which I have in my report.

MR. SLATER: Move to strike -- yeah,

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move to strike.

Did you not hear what I just said to you three minutes ago? I tried to be pretty emphatic about it, so I'm not really sure what you're trying to accomplish by continually talking about what the FDA decided based upon what I would tell you is a fraudulent presentation of information to the FDA --

MS. KABBASH: Adam --

MR. SLATER: So do me a favor, don't -- Maha, you know, with all due respect, do me a favor, Mr. Utalowski, please don't refer to that again unless I ask you about it, because I'm not asking you about what information was provided to the FDA in the actual 510(k). I'm not asking you that.

MS. KABBASH: Adam, can I ask you --

MR. SLATER: But you keep talking about it.

MS. KABBASH: I have a request for you: Could you just state for Mr. Utalowski again precisely the issue that you're asking whether or not he expects to have an opinion for at trial one way or the other?

MR. SLATER: Sure.

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MS. KABBASH: Can you restate that?
MR. SLATER: Sure.
MS. KABBASH: Because I would benefit from hearing that again.
BY MR. SLATER:
Q. I'm going to offer you a hypothetical and ask you to answer it "yes" or "no" or "I have no opinion": If, in fact, based on medical evidence, it was proven that there were new issues of safety and effectiveness for the Prolift and Prolift+M as compared to Gynemesh PS, if that was the fact -- and I'm asking you to accept it and assume that to be true -- would you agree with me that FDA regulations would have required a PMA to be filed for the Prolift and Prolift+M?
Three answers you can give me, "yes," "no," or "I have no opinion."
A. I don't think I can answer "yes" or "no." It's the way you're asking your question. You're asking if a medical -- there's a medical -- well, whose medical opinion? Your expert's opinion?
Q. A medical opinion that everybody in the world would believe to be accurate, objectively viewed.
A. And there's no opposing opinion?

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Q. No, there's no opposing opinion that's credible.
A. Well, I think that's where we have the impasse, because there -- there are differences of --
Q. It's a hypothetical. I can set the rule -- no, no, no. This is what you gotta understand about the litigation process: I make my hypothetical. You're stuck with it and you have to answer the question in the context of the hypothetical.
A. Then I can't answer your question.
Q. So based on my hypothetical -- you can?
A. I cannot answer your question then.
Q. So you have no opinion to answer that question; correct?
A. I have no opinion in regard to that question as it's been phrased, no.
Q. If Ethicon deliberately withheld material information regarding the safety and effectiveness of the Prolift and the Prolift+M that would have likely caused the FDA to determine that there were new issues of safety and effectiveness with the Prolift and Prolift+M, that would be a

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violation of FDA law; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, I like that question better, because you're putting the onus on FDA to make a final determination; and I think inasmuch as they make that determination of materiality and the lack of information, then I would -- I would tend to agree with you, yes.
BY MR. SLATER:
Q. You referred to the public health notifications and the panel meeting that took place with the FDA. You referenced that a little bit ago; correct?
A. Yes.
Q. Is it your assumption as an expert in this case that as of the time of the public health notifications and the panel meeting, the FDA was aware of all of the material risks connected to the Prolift and Prolift+M?
A. Well, just my understanding of panel meetings and the expertise on those panels and also FDA's contributing and there's outside -- opportunity for outside input at the panel meeting, be it industry, be it patients, be it whoever, that there's a lot of information disclosed at that point

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in time about what's going on with mesh --
MR. SLATER: Move to strike. Move to strike.
BY MR. SLATER:
Q. Is your answer "yes" or "no" to my question as to whether or not you drew that assumption?
A. You have to repeat the question, I guess. Sorry.
MR. SLATER: All right. I'm going to ask the court reporter to repeat it to you and listen carefully. It's a "yes" or "no" question. I'm not asking you why you're giving me the answer. Just give me a "yes" or "no," if you could, please.
- - -
(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: Well, "all" is pretty inclusive. I generally say yes, as a general statement.
BY MR. SLATER:
Q. You are not offering any opinions in this case as to whether or not the warnings and information about the risks with regard to the

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Prolift or Prolift+M were adequate; correct?
A. At what point --
MS. KABBASH: Objection.
THE WITNESS: At what point in time?
MR. SLATER: At any point in time.
THE WITNESS: Well, after the product was cleared, you had cleared labeling. That included whatever information was brought to bear during the review process, so -- and that's Prolift+M.
Now, Prolift, which was based upon Gynemesh PS labeling, I don't -- I don't think I made an opinion, rendered an opinion, regarding the adequacy of all the ingredients of that labeling.
BY MR. SLATER:
Q. And this is what I'm getting at: With regard to whether or not the warnings provided with regard to the risks and adverse events for the Prolift and Prolift+M in its labeling, whether or not that adequately disclosed all of the risks that Medical Affairs in Ethicon knew of, you haven't offered an opinion as to whether or not that labeling with regards to the warnings was adequate or not. Right?
A. I don't -- because it -- some of that

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incurs a medical position/opinion, no, I don't render a specific opinion regarding that.
I do render opinion regarding generally the regulatory elements of labeling and the compliance of the labeling generally with the regulations.
Q. When you offer an -- well, rephrase.
Can I just have the beginning of his answer read back, please?
- - -
(The court reporter read the pertinent part of the record.)
- - -
MR. SLATER: Okay. Move to strike from that point forward after the word "that," right after the part that you read back to me.
(Pause.)
BY MR. SLATER:
Q. You would agree with me that the patient brochure contained promotional information; correct?
MS. KABBASH: Objection.
THE WITNESS: I think we'll have to --
MR. SLATER: Obviously, I'm talking

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about the Prolift and Prolift+M patient brochures. They're promotional in nature to some extent; correct?
THE WITNESS: I don't believe so, not generally as patient brochures, no.
BY MR. SLATER:
Q. Did you read the letters and e-mails between the FDA and Ethicon during the 510(k) process carefully?
A. Yes.
Q. Did you read where Ethicon told the FDA that a brochure for Gynecare Prolift+M systems will also be utilized for education and promotion of this device in comparing it to the patient brochure for the Prolift? Did you read that sentence?
A. I didn't recall that, but, fundamentally, patient brochures are not promotional documents. They're information provided to patients as part of the process, informed consent process, with the doctor.
Q. Patient brochures are not supposed to be promotional. Right?
MS. KABBASH: Objection.
THE WITNESS: I guess I'd have to think about that a little bit. Are they -- are they

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prevented from being promotional?
Well, in one sense, I guess they include language regarding options and things like that, so there probably is an aspect of promotion there, but, I mean, it's very subtle.
BY MR. SLATER:
Q. Patient brochures are not supposed to be promotional; correct?
A. Informational -- more informational than promotional, not promotional in my experience. I mean, these are documents --
Q. In your --
A. These are documents at the doctor's office to be used in the conversation with the doctor and to select the most appropriate therapy with that patient.
Q. Really? Do you know that the patient brochure for the Prolift was on the Internet?
A. That's fine.
Q. It's a simple "yes" or "no."
A. I didn't recall that. It doesn't change what I just said.
Q. Why did you tell me it didn't change what you just said? Why can't you just answer a question in a direct way, sir? It's a simple

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question: Did you know before right now that the Prolift patient brochure was on the Internet, that Ethicon put it on the Internet? Did you know that?
A. I don't recall that. I may have known that.
Q. Are you aware that there are times where patients read the Prolift patient brochure not in the context of an informed consent discussion with their doctor? Do you know that that happened at times?
A. I'm not aware of that and I've seen no testimony on that, that I can recall.
Q. Did you know that Ethicon Medical Affairs knew that, in some cases, patients would read the patient brochure, but would not go through every aspect of it with the doctor?
It's a simple "yes" or "no." Did you know that or not?
A. I was -- I don't recall any testimony in regard to that.
Q. And all the testimony that you said that you read, did you read it carefully?
A. Did I read what carefully?
Q. The testimony that you read, the testimony you listed in your materials.

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A. Yes, I did, sir.
Q. You missed the part where the Medical Affairs people said that they knew that patients would, in some instances, read the patient brochure in the context of a discussion with their doctor? You just missed that?
MS. KABBASH: Objection.
THE WITNESS: I think I said, sir, that I don't recall. It doesn't mean I didn't read it.
BY MR. SLATER:
Q. If you selectively cited information in your report so that you would cite only information you thought was favorable to your opinions, as opposed to information that was contrary to your opinions, if the jury makes that finding, should they put any validity into your testimony at all?
MS. KABBASH: Objection; calls for a legal conclusion and calls for the expert to form some opinion on what jury instructions should be.
MR. SLATER: You can answer the question.
THE WITNESS: Repeat the question.
MR. SLATER: I'll ask the court reporter to read it back.

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- - -
(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: I don't know what to make of that question.
MS. KABBASH: That makes two of us.
MR. SLATER: That's fine -- really? I'll ask it more specifically to you.
BY MR. SLATER:
Q. Do you think that you should cite and rely on information selectively just so that you can find -- rephrase.
Do you think it's appropriate for you as an expert to just selectively cite information so that you're only citing the information that supports your opinions as opposed to, in a fair and balanced way, evaluating all the information?
A. Well, sir, I don't do that. As you note, for example, I talk about the FDA panel meeting with extractions of their opinions pro and con, so I -- I try and be as balanced as I can. Certainly I don't extract and cut and paste everything in what I've evaluated.

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Q. You know, do you not, that the IFU for the Prolift was changed over the course of time to include additional risks. You know that. Right?
A. Yes.
Q. If the risks that were added in later years were known in the very beginning, those risks should have been in the IFU from the very beginning. Right?
A. I think that's part of a medical opinion on the basis for their inclusion or exclusion.
Q. Well, if Medical Affairs made the decision to put a risk into the IFU in subsequent years and had exactly the same information available to it before the Prolift ever went on the market, then that information should have been in the Prolift IFU from the very beginning. Right?
A. No, I can't say that. I think there's reasons why information's in the IFUs. There are reasons why information's added to IFUs, so it changes over time.
Q. I need to understand this one. Okay? Even -- that one, I can't understand. Okay? So we're going to have to go through it a little bit.
Ethicon added language to the IFU for

the Prolift to the effect that one of the risks was pain with intercourse.

If the nature, severity of that risk was equally known to Ethicon before the Prolift ever went on the market, it should have been warned about in the IFU from the very beginning. Right?

A. Well, I examined deposition testimony regarding that item, for example, when there was testimony about what the Medical Affairs staff believed to be the case in regard to that, why or why that information -- why or why not that information was in labeling, so -- and I reference that in my report.

Dr. Hinoul, Dr. Robinson --

MR. SLATER: Can you answer my question now -- now I'll move to -- I'm going to strike that. Now can you just answer my question simply? It's a "yes" or "no" question.

THE WITNESS: Now repeat the question, please.

MR. SLATER: You can read it back, please.

- - -

(The court reporter read the pertinent part of the record.)

- - -

THE WITNESS: That's a medical opinion regarding whether it should have been there originally, why it wasn't there, so that was founded on medical opinion at that time, why it wasn't in there originally.

BY MR. SLATER:

Q. So you can't offer an opinion on that question; correct?

A. No, and my report speaks to Medical Affairs' decision making in regard to what was in the original IFU, what was in there, what wasn't in there.

Q. So you have no opinion on that -- it's very simple. So am I correct that you have no opinion on that?

A. I don't have a medical opinion on that, no.

Q. Well, you don't have a regulatory opinion on it either, apparently, because you're not giving me one. So am I accurate you have no opinion on that issue?

A. Well, the regulatory opinion is somewhat contingent upon the medical assessment of that.

Q. So, therefore, you have no opinion; correct?

A. I have no opinion about that.

Q. And, similarly, you have no opinion with regard to any of the risks that were added to any of the labeling for the Prolift or Prolift+M over the course of time as to whether or not those risks needed to be in the original versions of those documents; correct?

A. I don't have an opinion about --

Q. This is basically the catchall question -- this is basically the catchall question on the specific one we just went through.

Your answer would be the same for every single one of those things I would show you that were added later to those labeling documents; correct?

A. That's basically the case, yes.

(Pause.)

BY MR. SLATER:

Q. You offered an opinion that Ethicon's distribution of amended Prolift labeling after clearance was as timely as possible. That's one of the opinions you offered. Right?

A. Yes.

Q. Now, when you say it was as timely as possible, are you saying the company did everything it possibly could to get that labeling revised and out to doctors and patients as fast as possible; is that your understanding?

A. Yeah, I think everything considered -- I think Ethicon understood that -- I mean, all this was unexpected and certainly unintentional, so -- it wasn't their intention from what I saw that there be this delay, but factors came into play that kind of drew things out.

Q. To be fair, the factors that came into play that you just talked about was one screw-up after another in the process of developing those new IFUs and the timetables they set and then reset and then reset again; it was -- it's all -- it's practically a comedy of errors what went on before that IFU finally came out, isn't it?

MS. KABBASH: Objection.

THE WITNESS: Well, in my 38 years of experience at FDA and now working with companies, there's a bureaucracy in companies that has to be dealt with and a process; and things that you think, sir, might take a day or two, in fact, there's -- you gotta get the lawyers involved and you gotta do

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all that. It takes -- it takes an amount of time.
BY MR. SLATER:
Q. If Ethicon knew that it was going to take time -- well, rephrase.
To the extent that Ethicon knew that there was important information that it was going to add or change from its IFU and patient brochure, while those documents were being revised and prepared, Ethicon had the means to get that important information to doctors, correct, and to patients; correct?
A. Yes, I think, for example, they -- in training, they were talking about these things.
Q. Well, the training wouldn't get to a doctor that had already been trained and had been relying on the Prolift IFU and patient brochure for over three years in all cases. Right? There's a lot of doctors that would not hear the new training. Right?
A. I just gave you one example. There's other means through the sales staff and others to get information out. So there's vehicles to do it.
Q. Ethicon had the ability, if it so chose, to get the important information about what was being changed in the IFU and patient brochure

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out to doctors right away if it wanted to.
It could have done a dear doctor letter. It could have had its sales representatives pass this information on. It could have been done immediately and quickly. Right?
MS. KABBASH: Objection.
THE WITNESS: I'm not so sure it would have been immediate or quick. I think there's -- no matter what gets issued by a company, be it training, be it dear doctors, be it whatever, that companies have a process for evaluating that information, for getting medical and legal opinion, and that's just the way the process worked, so -- I don't know how long it would have taken.
BY MR. SLATER:
Q. When there's -- when there is important medical information about the risks of a procedure or a device like the Prolift and the company knows that the IFU and the patient brochure in circulation are not accurate in some material respects, the company has an obligation to move as quickly as possible, as fast as possible, to get that information to doctors and patients right away, because patient safety can be jeopardized by any unreasonable delay; correct?

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MS. KABBASH: Objection.
THE WITNESS: I think the process should be moved along. I think -- if I'm not mistaken, I think even Ethicon informed FDA that there would be some delay here, and FDA didn't express any problem.
BY MR. SLATER:
Q. This was a -- this was a 510(k) process the Prolift and Prolift+M went through, not a PMA process; correct?
A. Yes.
Q. If Ethicon left a patient brochure in circulation -- rephrase.
As this process unfolded with the FDA in 2007 and 2008, Ethicon recognized that the patient brochure for the Prolift was going to have to be changed in some material respects; correct?
A. Yes, at some point in time in the discussions with FDA.
Q. At that point, there was no requirement that the patient brochure be provided to doctors and patients. Right? Ethicon could have stopped printing it and stopped circulating it; correct?
A. Well, I think you want to wait

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certainly till the very, very end of the process with FDA to make sure that, at the last moment, FDA doesn't call you up on the phone and say, wait a minute, you know, in addition, add this or that.
So you want to, first of all, make --
Q. That's not what I asked you. My question was -- move to strike.
My question was very simple: Ethicon could have stopped circulating the patient brochure at the snap of a finger once it recognized that information in that patient brochure had to be changed. Right?
MS. KABBASH: Objection.
MR. SLATER: They could have stopped --
THE WITNESS: Well, a company could stop --
BY MR. SLATER:
Q. -- sending it out to the doctors. Right?
A. A company could stop selling a product, yes.
Q. I didn't say stop selling the product. I said the company could have stopped circulating the patient brochure at the snap of a

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finger; correct?
A. Well, the patient brochure goes with the product.
MS. KABBASH: The patient brochure.
THE WITNESS: Oh, the patient brochure, rather.
MR. SLATER: Didn't you tell me that -- sorry.
THE WITNESS: Okay. Patient -- okay. Patient brochure.
MS. KABBASH: Sorry. We had a disconnect.
THE WITNESS: Sorry. A disconnect -- the patient brochure could be stopped, yes.
But again --
MR. SLATER: You also --
THE WITNESS: Sorry. I didn't finish -- but the patient brochure was also being assessed by FDA; and until the very last moment of FDA's review, I think, as a company, you probably want to keep moving the current patient brochure until all is said and done by FDA on that brochure.
BY MR. SLATER:
Q. If at any point Ethicon knew that any statement in the patient brochure was false or

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misleading in any material way, Ethicon had an obligation not to use that patient brochure; correct?
A. If -- if Ethicon believed any information was false and misleading?
Q. Yes.
A. If that's --
Q. Yes.
A. -- the determination by the responsible party that it's false and misleading, yes, I think that's a problem.
Q. And needs to be not utilized at all; correct?
A. Well, you -- I guess you don't want to keep the patients in the lurch, so -- I'm just thinking of the logistics there.
Well, sir, you've got product in the marketplace that's being implanted. You have to provide them some information.
Q. Well, the product didn't need to be on the marketplace, did it?
A. No, there was no obligation by Ethicon to market the product. That was their decision.
Q. And if Ethicon had a question about

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whether or not it could -- well, rephrase.
And to the extent that Ethicon could not provide an IFU and a patient brochure that was accurate in all respects and was not false or misleading in any respect, they shouldn't have sold the device during a time period when they couldn't do so. Right?
MS. KABBASH: Objection.
THE WITNESS: That's a lot of "ifs" there.
MR. SLATER: Yeah, let me ask the question differently because it's a convoluted question.
BY MR. SLATER:
Q. If Ethicon did not have a patient brochure or an IFU for the Prolift, other than a version that it knew and believed was false or misleading in some material respects, Ethicon should have not sold that device during that time period until it could put out the device with a truthful IFU and a truthful patient brochure; correct?
A. An interesting question. That's -- if -- if Ethicon thought the labeling was false and misleading.
Q. Right.

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A. You know, a company decision could be, let's get the new IFU and patient brochure out as quickly as possible, we've got product in the doctors' hands, on the shelves, you know, there's a logistics issue there.
Q. Which could be easily solved by sending a dear doctor letter immediately and having the sales representatives tell the doctors immediately, stop using the Prolift until we get you accurate labeling. Right?
A. Well, sir, then you have to assess the medical impact of that. Doctors have the mesh on their shelves. They don't -- they don't have other product, perhaps.
So are you going to put a patient at risk, even more risk, than having labeling that may have a statement in there you don't like?
I don't know if you're understanding what I'm saying. Obviously you don't understand patient risk --
Q. No, I don't understand. Are you telling me that would be the decision the company should actually legitimately make, well, you know what? It's better to put the Prolift out there on the market and leave it on the market even though we

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know that our labeling is false and misleading in some material ways?

You think that that's acceptable for the company to say, that's okay because we want to make sure that people can use Prolifts if they want to put them in their patients? You think that's the right decision?

A. I think, sir, it's a more complex decision than you're making it out to be, so, medical/legal --

Q. Really?

A. Yes, I think so, sir.

Q. Well, how about this? See, what you're worried about is the company making money and so let's put that aside for a second.

A. No, no, sir.

Q. No, you are. Let me go ahead.

MS. KABBASH: Move to strike the statement.

BY MR. SLATER:

Q. If the Prolift wasn't on the market, every woman that got a Prolift could have been treated by an alternative procedure; correct?

A. That's a medical decision, sir, between the doctor and the patient.

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Q. You don't know, as you sit here as a professed expert in this case, that there were alternative procedures to the Prolift; you think that was the only way a woman's prolapse could be treated, with a Prolift, is the only way in the world?

MS. KABBASH: Objection.

MR. SLATER: Is that what you're telling me?

THE WITNESS: No, sir, what I'm saying is, the decision to use a product or not to use a product is a decision between a doctor and a patient. It's not between her lawyer and the patient.

MR. SLATER: That's not what I asked you about, though -- see, why -- but I never asked you about that, so let's stick with my question. Okay?

MS. KABBASH: Adam, you have five minutes left on the tape.

MR. SLATER: Okay. Thanks.

BY MR. SLATER:

Q. One of the things Ethicon could have done was send out a letter to every doctor and have the sales representatives copy every doctor within

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24 hours, saying, just so you know, that IFU and that patient brochure for the Prolift that you have and that you've been relying on is false and misleading in certain material respects; it's going to take time to get the new ones out, so until then, we're just telling you, there are some aspects of this that you cannot rely on.

That could have been done within 24 hours and then doctors could have made the decision do I want to still use this device or not. That was an option that Ethicon had; correct?

MS. KABBASH: Objection.

MR. SLATER: Or -- or -- well, actually, answer that question. Go ahead. Stick to that question first.

THE WITNESS: I think it's an option. Was it a feasible option? Was it justified? You know, that's another question.

BY MR. SLATER:

Q. And, in fact, if Ethicon had taken that option, then the doctors could have made the decision to say, I don't care or to say, you know what, let me find out what this information is that's being changed, because it may impact on the next patient I think about giving a Prolift.

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Maybe there's something in that IFU that I think is true and it turns out it's not or there's some risk that hasn't been disclosed yet that I'm about to learn about that may make an impact on patient care.

Then you put the decision in the doctors' hands of what to do. Right? That's the best way to handle it. Right?

MS. KABBASH: Objection.

THE WITNESS: Well, I'll agree with you that the decision to use a product is between a doctor and the patient. So I agree with you there.

As far as the other aspects of your question, we're getting pretty far down the road of getting into the mindset of a doctor and what they believe, don't -- don't know, what they know, so, you know, it's getting somewhat -- maybe too hypothetical here.

BY MR. SLATER:

Q. Is it acceptable for a medical device manufacturer to sell a device, accompanied by an IFU that the company knows to be false or misleading in certain material ways, and to also put out a patient brochure at the same time that the company knows to be false or misleading in certain material ways? Is

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that acceptable?
A. If the company's made that determination, the responsible party at the company, that it's false and misleading, I think that's a problem.
Q. It's completely unacceptable. Right?
A. It's not something when I was at FDA that I'd want a company to be doing, if that's their decision, their conclusion regarding their own labeling.
Q. If a company knew its own labeling to be false and misleading in certain material ways, yet used that labeling and continued to sell the device with that labeling, that's an outright violation of federal law. Right?
A. Well, I guess the premise for your question is, is it false and misleading, has the company determined that, have they made a conscious decision to move that labeling, I think that's a problem.
Would it be a violation of law? FDA will take its own determination as I would -- I would, too, in assessing the labeling, trying to render an opinion whether it was false and misleading, whether I can do that, whether it's a

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medical opinion.
So I don't know. You know, that -- that kind of incurs a lot of different considerations there.
Q. Well, if after all that analysis, it was clear in my hypothetical that the company was right, that its labeling was false and misleading in certain material ways, then it's a violation of federal law to sell that device with that labeling. Right?
A. I think it could be.
Q. Well, it would be. Right?
A. Could be. I mean, you're talking about materiality, false and misleading. You know, those are final conclusions. I don't know what to make of that, really. If you want to talk about examples maybe --
Q. Well, this is -- this is what I want you to make of it: Assume that the labeling for the Prolift, the IFU and the patient brochure, was false and misleading in multiple material ways and omitted to provide material information that should have been included. I'd like you to assume that.
And I'd also like you to assume that the information -- that this information was known

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to Ethicon Medical Affairs.
Under those circumstances, the Prolift should not have been marketed with that labeling; correct?
A. You know, perhaps. Some of this information is information that becomes known by the company and they then want to get it into the labeling at the next revision, so, you know, the company tries to cure --
Q. No, no, no, we're not going to go down that road. Whoa, whoa, whoa, we're not going to go down that road. We don't have a lot of time here. Please answer -- I move to strike. Please answer my question.
A. Well, companies -- companies are trying to improve labeling all the time, so, I mean, what is false and misleading, what needs to be amended or corrected or clarified in labeling -- you know, is it false and misleading? I mean, those are strong words.
Q. Okay. I move to strike. I just gave you a hypothetical.
Under the hypothetical, based on your own definitions, the labeling was false and misleading; in certain respects, it omitted to

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provide important material information about risks, which you would define to meet those terms, all that falls in place, so there's no interpretation in this answer.
Based on that hypothetical, the Prolift should not have been marketed; correct? Not with that labeling. Right?
A. If it's the conclusion of the company that their labeling is false and misleading, by the most responsible party, and the product's not been marketed yet, the labeling shouldn't be sent.
If the labeling's out there, they find an issue, there -- an area for improvement, an area for correction, that's usually done in the course of labeling modifications.
Q. If it was known before the Prolift was even launched, then the Prolift should not have been marketed with that labeling; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, what was the conclusion by Ethicon, the most responsible party? Was it that their labeling is false and misleading --
MR. SLATER: I just told you my hypothetical. Wait. Sir, I told you, the

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hypothetical remains.
The most responsible party, the Medical Affairs director of Ethicon, Women's Health & Urology, the person responsible to know all the important medical information and to sign off on it, knew that the labeling was false and misleading and omitted to provide material information, under that scenario, the Prolift should not have been sold with that labeling; correct?
THE WITNESS: Well, I think we're coming full circle with where you started today, and that's that business about maybe about -- in regards to the business regarding, well, IFUs are in the box, here, there's some statement that this should be in labeling, it didn't get into labeling until two, three years later maybe. I think that's the angle you're going here.
I -- I think if there's a decision by a company that labeling's false and misleading, the product's not been marketed yet, there's an opportunity to make -- to correct that labeling, the feasibility, the logistics, then you do it.
If the -- if the truck's left and the product's distributed, then you gotta take a different tact.

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MS. KABBASH: Adam, the tape's running out.
MR. SLATER: Okay. You can change the tape. And I'll be done soon.
MS. KABBASH: Okay.
THE VIDEO TECHNICIAN: Time now is 3:50 -- 2:55. We are going off the record -- actually, 3:55. We are going off the record. This is the end of disc number two.
(A recess was taken from 3:55 p.m. to 4:07 p.m.)
THE VIDEO TECHNICIAN: The time now is 4:07. We are back on the record. This is the beginning of disc number three.
BY MR. SLATER:
Q. I'd like to pose a hypothetical to you: In December 2008, a woman goes to a doctor, has her prolapse evaluated and the doctor says, "I'm recommending the Prolift to you," and she has a Prolift put into her body in December of 2008.
However, at that time, both the doctor and the patient were relying on the IFU and the patient brochure that Ethicon had already acknowledged needed to be changed in certain material ways, and they didn't know that these

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documents were going to be changed; and if they had known that, they would not have gone forward with Prolift surgery unless and until they saw the updated labeling.
The woman then went on to suffer severe complications of multiple erosions and re-prolapse of her organs and had to undergo at least four more operations to treat not only the eroding mesh, but also to remove mesh and to try to fix her vaginal cavity, which had become distorted and abnormally small as a result of these complications.
Taking that hypothetical situation as truthful, what do you say on behalf of Ethicon, for whom you're the expert in this case, to that woman who would not have had this Prolift put in her body if the company had just told her doctor that the labeling was being updated?
MS. KABBASH: Objection. Objection; and beyond the scope of Mr. Utalowski's testimony as a regulatory expert in this case.
THE WITNESS: It's not really a regulatory response. I -- I understand the situation. I'm not the spokesperson for Ethicon. I'm their regulatory expert.

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BY MR. SLATER:
Q. What do you say to that woman as an expert in this case, based on the fact that her and her doctor relied on labeling the company was in the process of changing and the company didn't tell them, and the doctor would not have used the Prolift with her if he had known the labeling was being changed? What do you say to her?
MS. KABBASH: Objection. Same objection.
THE WITNESS: Sir, I'm the regulatory expert in regard to this particular product. I'm not Ethicon's spokesperson involved in the particular episode you've identified.
BY MR. SLATER:
Q. Well, you -- this is within your -- rephrase.
This does come directly within your expertise, because the doctor and patient were relying on labeling the company knew to be false and misleading in certain material ways, but they didn't know that because the company didn't tell them.
What do you tell that patient? What do you tell her?
MS. KABBASH: Objection; outside the

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scope of Mr. Utalowski's role as a regulatory expert in this case.
MR. SLATER: Please stop saying that. It's not true. Please answer the question.
MS. KABBASH: It is true.
THE WITNESS: I'm not the spokesperson for Ethicon. I'll -- I'll -- I speak to the regulatory aspects regarding the particular litigation, but I'm not one to interact with the patient or speak to the patient directly.
BY MR. SLATER:
Q. Well, obviously, I'm not going to present you to this patient, so don't worry. She's not going to come walking into the room with you right now.
My question is this: As an expert, what do you think would be the appropriate thing for Ethicon to say to that patient who got a Prolift put in her body because the company didn't tell her doctor that the false and misleading labeling that he was relying on was being changed?
MS. KABBASH: Objection.
THE WITNESS: Sir, you're asking me to articulate a response that a company would make to a patient in regard to her particular condition.

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That's not my role as I sit here.
BY MR. SLATER:
Q. Well, you're an expert, so I'm asking you, what should the company say to the patient?
MS. KABBASH: Objection.
THE WITNESS: I'm not a regulatory expert in -- I'm a regulatory expert in regard to -- to a particular product. I'm not their communications person or articulating a statement to a doctor or patient.
BY MR. SLATER:
Q. Well, you realize that -- you realize that the things you're offering opinions on, this Prolift and Prolift+M, you realize there's women who suffered catastrophic permanent injuries as a result of complications from those devices. You know that. Right?
A. Women have had complications, and many women who have probably went -- gone on to have satisfactory outcomes, so -- I understand that. That's with every device.
MR. SLATER: Move to strike from "and many" forward.
I'm not sure why you're telling me about things I'm not asking about, so let's just try

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to stay really focused here.
BY MR. SLATER:
Q. You understand, as a regulatory expert offering opinions with regard to the Prolift and Prolift+M, that the range of risks with those devices from the first day they were marketed included catastrophic injuries to women of a permanent and enduring nature for the rest of their lives. You know that's part of the risk profile for those devices; correct?
A. I understand there were risks with the product, as there are with other devices, yes.
MR. SLATER: Move to strike from "as are" forward.
BY MR. SLATER:
Q. Can I ask you a question? Why did you add on the thing at the end when you know I'm not asking about other devices? Tell me why you just did that.
A. Just placing it in proper context.
Q. Why did you -- why did you do it -- when you know that I'm asking you for an answer to one specific question, why did you throw in information that had nothing to do with my question?
A. Well, that's your opinion, has

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nothing to do. It's my opinion it does.
Q. Did you think it was helpful for your client if you added on the talking point that you thought might be favorable to their litigation position?
MS. KABBASH: Objection; move to strike his question and his editorial statement. Adam, if you want to ask him a question with regard to regulatory --
MR. SLATER: I just did. Answer the question.
MS. KABBASH: I beg to differ.
MR. SLATER: This is -- hang on. This is a seasoned expert -- hang on. This is a seasoned expert who's being paid a lot of money by your clients to be an expert --
MS. KABBASH: He is --
MR. SLATER: -- so I'm going to ask him why he did what he did.
MS. KABBASH: He's a --
BY MR. SLATER:
Q. Did you think that was a good thing from a litigation perspective to try to help your client out to throw in the part that you knew wasn't responsive, the little talking point at the end?

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MS. KABBASH: Objection; argumentative.
MR. SLATER: Is that why you did it?
THE WITNESS: I think it's appropriate to put labeling and experience with a product in context to -- as people try to understand risks with products, that every product presents risks.
BY MR. SLATER:
Q. Now, we're going to try this one more time and what I'm going to ask you to do, in my politest voice, is to please answer my question directly, limited only to the question. Okay?
You know that the risks of the Prolift and Prolift+M include catastrophic vaginal and pelvic injury to a patient; correct? You know that that can occur as a direct result of the Prolift and Prolift+M; correct?
A. Well, I don't think the adverse effect is stated quite that way, if we look at the labeling.
Q. I'm not asking you about the labeling.
A. Well, sir --
Q. So I move to strike.

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A. Well, sir, you're characterizing the adverse effect. I'm saying, let's look at the labeling and see what it says.
Q. But you understand that one of the claims in this case is the labeling is wholly inadequate because it doesn't reflect the full scope of serious risks that were known to the company. So why would I defer to labeling that I know is completely inadequate?
So let's stick to my question and let me take a step back. You read the testimony, you claim, of Pete Hinoul and David Robinson and other Medical Affairs people. Right?
A. Yes.
Q. Based on that testimony, you understand that the risks to women from the Prolift and Prolift+M include catastrophic vaginal and pelvic injury; correct?
A. Well, I don't recall specific testimony using the term "catastrophic." It's not that I deny that would be the case. I just don't recall the labeling nor the testimony referring to that. If you could direct me further, I'd be happy to look at that.
I don't deny the fact that there's

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adverse effects.
Q. You don't deny that there's adverse events that cause what a layman would cause -- rephrase.
You don't deny that those adverse events include injuries that a lay person could reasonably characterize as catastrophic; correct?
MS. KABBASH: Objection.
THE WITNESS: All I would opine on is regarding whatever testimony was or medical opinion. I wouldn't render a medical opinion on that or hazard a guess on what I would call catastrophic in this instance. That's a medical opinion.
BY MR. SLATER:
Q. Did you make any effort to learn the scope of risks that Ethicon Medical Affairs actually knew existed with the Prolift and Prolift+M?
A. I've seen the deposition testimony as to what was known, what was testified as to what they knew.
Q. And you understand from reading that testimony that women could suffer from catastrophic injuries to their vagina and pelvis due to the Prolift and Prolift+M. You understand that; correct?

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A. If that's testimony that I've seen -- I don't recall, but if that's testimony by the medical staff of Ethicon, I'm not going to argue it.
Q. If for some reason Ethicon could not produce labeling for the Prolift or Prolift+M which was not false and misleading in material respects, during that time period when they couldn't do that, they should not have been selling the Prolift; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, I -- I agree that if Ethicon and/or FDA determined the labeling was false and misleading, that they needed to remedy that.
Now, the method of doing that, I don't know if I can opine on every -- any method -- any and every method. We've talked about a couple.
BY MR. SLATER:
Q. If for some reason Ethicon could not remedy this false and misleading information, couldn't get all the doctors and patients to know the truth, then Ethicon should not have been selling the Prolift during that time period. Right?
MS. KABBASH: Objection.
THE WITNESS: They would have to

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remedy the labeling. I mean, that's what -- that's what I can say. Did they need to stop selling the product while they're remedying? I wouldn't go so far as to say that.
BY MR. SLATER:
Q. It's one option. Right?
A. It's one option, yes.
Q. Let's look at Exhibit 10.
A. Okay.
Q. Tell me what Exhibit 10 is.
A. Well, I requested from Becker & Associates, where I work, all the invoices related to Butler Snow and this is what I received. So I note most of it's my time, but there is other additional charges for one of my associates.
Q. That's Meaghan Bailey?
A. Correct.
Q. So other than the little bit that's attributed to Meaghan Bailey, all of the other billings are your total billings with regard to the work you've done with regard to the Ethicon pelvic mesh devices?
A. That's correct.
Q. When did you start reviewing TVT information?

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A. Well, actually, I received TVT information early on after being engaged, but I think it mainly served as background information for the mesh, and more recently, additional information has been forthcoming on TVT.
Q. Most of the billing reflected in Exhibit 10 would relate to the Prolift and Prolift+M?
A. I'd say that's the case, yes.
Q. And do you intend to act as an expert with regard to the TVT devices in litigation?
MS. KABBASH: Objection.
THE WITNESS: Well, I don't know. That's Butler Snow's decision.
BY MR. SLATER:
Q. I'm asking what you intend to do.
A. If asked --
MS. KABBASH: Objection.
THE WITNESS: -- I'll consider it. I haven't formulated any opinions or anything in regard to the material.
MR. SLATER: I don't have any other questions.
MS. KABBASH: Okay. I just have two or three questions.

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EXAMINATION
- - -
BY MS. KABBASH:
Q. Mr. Utalowski, you were asked by plaintiffs' counsel some questions regarding what the obligations of a Regulatory Affairs associate within the company is when he or she is provided with suggested warnings by a Medical Affairs associate.
Do you recall that line of questioning?
A. Yes.
Q. Is there a regulatory requirement that would govern the regulatory associate's obligations under those circumstances?
A. Not specifically and directly.
Q. Is that a matter of internal company policy?
A. That's policy --
MR. SLATER: Move -- objection.
THE WITNESS: That's -- relates to policy and procedure that the company creates, that a Regulatory Affairs person would then follow.
BY MS. KABBASH:

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Q. But there's not a regulatory requirement that governs that.
A. No, not specifically.
MR. SLATER: Objection.
BY MS. KABBASH:
Q. Can you pull out your report, which is, I believe, Exhibit U-4?
Now, you've stated several times today that you are not holding opinions that would require a medical analysis; correct?
A. Yes.
Q. If you can look on page 67 of your report and specifically look at opinion number 5, plaintiffs' counsel asked you whether you held any opinions with regards to the adequacy of labeling and I just want to ask you one thing.
Here, you state the opinion on page 67 of your report that Prolift instructions for use labeling, prior to implementation of FDA-requested changes, was in compliance with prescription device regulatory requirements. The labeling was not misbranded.
And then you include underneath that four bullet points setting forth examples of what you mean.

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Do you still stand by the opinions as stated in point number 5 on page 67 of your expert report?
A. Yes.
Q. Are there any questioning that you received by plaintiffs' counsel today that alters opinions set forth in section 5 on page 67 of your report?
A. No.
Q. Okay.
You were asked several questions today about patient brochures. If a patient were to read a patient brochure outside of a doctor's office or access that patient brochure on a website, would that change any of your opinions in your report with regard to the adequacy of the labeling?
A. No.
Q. Would it change any of your opinions regarding whether or not those patient brochures -- strike that.
Would it change your opinion that the patient brochures for Prolift were not misbranded?
MR. SLATER: Objection.
THE WITNESS: It wouldn't change the opinion.

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BY MS. KABBASH:
Q. If you could turn to the next page, page 68 --
A. Okay.
Q. -- opinion 6 of your report states --
MR. SLATER: Wait. One second. One second. Maha, one second. What's this music I'm hearing? Are you guys hearing that, too?
MS. KABBASH: Yeah, we are. I thought that was on your end.
THE WITNESS: It's at the alternate site.
MR. SLATER: No, it must be coming through the other --
MS. KABBASH: Hey, Andrew?
MR. DONELAN: Yeah?
MS. KABBASH: Do you have any music at your site?
MR. SLATER: Can you mute your phone again?
MR. DONELAN: Yeah, there's no music in here.
MS. KABBASH: You know what? Can you -- so were you -- you were muted all that time. Right?

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MR. DONELAN: Yeah, I was muted. I'll mute it again, but there's nothing going on in here, so --
MS. KABBASH: Okay. Yeah. It's weird.
Oh, it seems like it just stopped.
THE WITNESS: Okay.
MS. KABBASH: All right.
MR. SLATER: Okay.
THE WITNESS: Where are we at now again?
BY MS. KABBASH:
Q. Mr. Utalowski, if you'll look at page 68, number 6 --
A. Uh-hum.
Q. -- your opinion there states, "PROLIFT patient brochures labeling and help-seeking communication, prior to FDA review were in compliance with regulatory requirements. The brochures labeling and the help-seeking communication were not misbranded."
And then below that, you set forth five bullet points providing further detail on your opinion.
Is anything in section 6 in your

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opinion altered -- or does your opinion change in any way because of the possibility that a patient may -- may read a patient brochure outside of her doctor's office or access it on the Internet?
A. It doesn't change my opinion.
MS. KABBASH: Okay. No more questions.
MR. SLATER: Let me just follow up on the last couple of questions.
- - -
EXAMINATION
- - -
BY MR. SLATER:
Q. With regard to whether or not the labeling for the Prolift or Prolift+M was adequate, if we focus on the disclosure of -- or discussion of medical information in those documents, you're not in a position to offer an opinion as to the adequacy or inadequacy of that medical information, because you're not forming any opinions that would require medical knowledge; correct?
A. No, for example, on number 5, I refer to the medical rationale for statements made or statements not made, so that's one of my foundations for my opinion. But I have not directly assessed

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those statements.
Q. Well, actually, what you say is, "Ethicon had a regulatory and medical rationale for the statements in the IFUs." You make that statement. Right?
A. Correct.
Q. In your report?
A. Yes.
Q. The fact that there may have been a rationale for the statements doesn't mean that they're not false and they're not misleading. Right? The rationale could have been wrong; correct?
A. Well, that's subject to medical opinion. Is it possible? That's subject to medical opinion.
Q. So whether or not the medical rationale for the statements made in the IFUs or the patient brochures or any other labeling, whether or not that rationale was adequate, whether or not it was complete, whether or not it was truthful or false, that's not something you're going to form an opinion on; correct?
A. Not if it requires a medical assessment.

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Q. You have no experience working internally within a medical device manufacturer; correct?
A. Well, yes, as a consultant, but you mean as an employee of a medical device manufacturer? How do you mean, sir?
Q. Well, let me clarify.
You have never worked as an employee at a medical device manufacturer; correct?
A. No, only as a consultant to manufacturers.
MR. SLATER: Move to strike after "No."
BY MR. SLATER:
Q. Well, actually, let me ask it again because it's a double negative.
Am I correct that you have not worked directly for a medical device manufacturer or prescription drug manufacturer as an employee?
A. Correct.
Q. I saw some reference in your prior deposition to the fact that a Johnson & Johnson company that you consult for, you handled a matter having to do with lack of compliance with FDA regulations? Which company is that?

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A. Advanced Sterilization Products.
Q. What's the name of the company?
A. Advanced Sterilization Products, ASP.
Q. Oh, got it. Advanced Sterile -- what was the -- what's the compliance problem?
A. I don't think I can get into it directly because it incurs the need for me to talk about trade secret and confidential commercial information.
Q. Tell me in a general sense what's the issue.
MS. KABBASH: Mr. Utalowski, if there's a general way that you feel like you can answer the question, answer it.
THE WITNESS: Well --
MS. KABBASH: And if you can't, you can't.
MR. SLATER: Let me make it clear. I frankly don't care whether it's confidential or not. I'm going to get answers to my questions. I want to understand the situation where he's working as a consultant for a J & J company.
BY MR. SLATER:
Q. Let's start with the general: Can you tell me what the general regulatory issue is?

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MS. KABBASH: That's fine, Adam, but he cares and he has a right to care, and I care. So if he can answer your question --
MR. SLATER: Yeah, well, it's litigation and he's under oath, so I'm going to need answers to my questions.
MS. KABBASH: That's fine. If he can answer it in a way that does not infringe on trade secrets, then by all means, he should do so.
THE WITNESS: It concerns good manufacturing practice issues generally, not litigation.
BY MR. SLATER:
Q. And you advised this company that you believed that they were in violation of FDA regulations; correct?
MS. KABBASH: Objection.
THE WITNESS: I was assisting them in regard to their response to FDA in regard to violations.
BY MR. SLATER:
Q. And you felt in that situation that there were violations of FDA regulations; correct?
MS. KABBASH: Objection.
THE WITNESS: Well, FDA made that

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determination already, so I was helping them respond to those.
BY MR. SLATER:
Q. You were -- you agreed with the FDA that there were violations of FDA regulations; correct?
MS. KABBASH: Objection.
THE WITNESS: I didn't -- didn't do an independent -- well, actually, at FDA, I was involved in -- in regulatory actions concerning the company. So I was involved in determining the violations at the outset.
BY MR. SLATER:
Q. So the violations, you determined while you were working at the FDA; and then when you left the FDA and became a consultant, you're now consulting for that company to help them to comply with the regulations that you found they were in violation of when you worked for the FDA.
Do I have that right?
A. Yes, I think so.
Q. So you have worked for the FDA on a specific regulatory compliance matter involving Advanced Sterilization Products, a company owned by Johnson & Johnson; correct?

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A. Yes.
Q. You made a finding that this company was in violation of FDA regulations; correct?
A. As an FDA Director of Compliance, yes.
Q. Then you left the FDA, went into private practice as a consultant, and you were hired by the same Johnson & Johnson company to consult with them on how to deal with the regulatory violations that you had found when you were working at the FDA; correct?
A. Yes. And so?
Q. Is your involvement with this matter disclosed to the FDA?
A. It doesn't have to be.
Q. Is it?
A. No. There's no requirement that it be disclosed.
Q. The answer is, it has not been disclosed to the FDA that you are working as a consultant with Advanced Sterilization Products on this matter; correct?
MS. KABBASH: Objection.
THE WITNESS: That's correct, and there's no requirement for that.

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MR. SLATER: Move to strike from "and" forward.
BY MR. SLATER:
Q. How much money have you been paid in connection with that matter?
A. Actually, very little. My involvement was limited --
Q. I asked you for a number, sir. Can you just tell me the number?
MS. KABBASH: Adam, calm down. He's getting to it.
THE WITNESS: I can't say. I --
MR. SLATER: I'm pretty calm. I just want to know the number.
THE WITNESS: I can't recall --
MR. SLATER: I want to know how much you've been paid in connection with that matter.
THE WITNESS: I can't recall. I'd say around or less than $5,000.
BY MR. SLATER:
Q. Now, is the money -- well, rephrase.
Are your services being billed through you personally or through a consulting company?
A. It depends on when I was working on

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the issue. It may have been -- oh, it would have been billed through a consulting company, yes, I believe.
Q. Which company?
A. Either the current company I'm with, consulting group, or the prior consulting group I worked with.
MR. SLATER: All right. We're going to make a request for all those billing invoices that have been served on Johnson & Johnson and proof of payment. Cheryll's going to send an e-mail today to confirm the request.
MS. KABBASH: We will respond to that request when we receive it in writing.
BY MR. SLATER:
Q. Now, are there any conflict of interest rules that you're aware of that could potentially be implicated by your side-switching from the FDA to then be a consultant for Advanced Sterilization Products in this situation?
A. No, none whatsoever.
MS. KABBASH: Objection.
BY MR. SLATER:
Q. Did you study the question before you took on this assignment?

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A. I'm familiar with the post-employment restrictions. It didn't meet the criteria.
Q. So the FDA conflict of interest rules let someone like you work at the FDA, find violations against a company, then leave the FDA and then go to work for the same company to help them to address the violations that you found. That's -- that's correct? That's what you understand with regard to the conflict of interest rules at the FDA?
MS. KABBASH: Objection.
THE WITNESS: Yes, and my role is to help them make the best product they can.
MR. SLATER: That's all I asked you. It's a "yes" or "no" question.
THE WITNESS: Yes, the --
MR. SLATER: What's that?
THE WITNESS: -- the post-employment restrictions enable me to do that.
BY MR. SLATER:
Q. If I suggested to you that the post-employment restrictions at the FDA are far from rigorous, you wouldn't disagree with that, would you?
MS. KABBASH: Objection.
THE WITNESS: Oh, I think they are,

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sir. There are a number of post-employment restrictions, and I pay attention to each and every one of them.
BY MR. SLATER:
Q. Are you permitted to disclose to Advanced Sterilization Products anything that you know about the internal deliberations at the FDA with regard to the regulations that you found existed while you were still working there at the FDA?
A. In regard to an open enforcement action, that would be a problem, but I have not done that.
Q. When you say it would be a problem with regard to open enforcement action, what do you mean by that?
A. If FDA's taken a process to seize or to enjoin a company and that process is still in effect.
Q. If there's a potential for an open enforcement action, those rules would be implicated; correct?
A. Well, inasmuch as I was involved with that action, that specific action.
Q. If, in fact, you have disclosed

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anything about the internal deliberation process, anything that would not be public, outside the FDA -- when I say public, meaning outside the FDA -- if you've disclosed any sort of that information to Advanced Sterilization Products or their attorneys or anybody else with regard to that matter, you violated FDA post-employment practices rules; correct?
MS. KABBASH: Objection.
THE WITNESS: You got a lot of "ifs" there. If it's an open enforcement --
MR. SLATER: If they're all correct, then it's a violation. Right?
THE WITNESS: If it's an open enforcement action, if I've disclosed internal deliberations -- I think they have to be material, that's how FDA's interpreted that -- then that could be a problem, yes.
BY MR. SLATER:
Q. Before you went to work on behalf of Advanced Sterilization Products in this nondisclosed consulting role, don't you think the right thing to do would have been to disclose to the FDA that you were considering consulting for this company and then ask the FDA if they would permit it?

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MS. KABBASH: Objection.
THE WITNESS: There's no requirement for that and there's no requirement for FDA to permit anything from a former employee.
BY MR. SLATER:
Q. So the reason, basically, that the FDA has these rules that allow you to do this consulting work for Advanced Sterilization Products is basically because the rules are not designed to block people from leaving the FDA and going to work in industry; you want to make it as easy as possible so that when you all leave the FDA, you can make a lot of money getting paid by the companies you are supposed to be regulating. Right?
MS. KABBASH: Objection.
THE WITNESS: That's a ridiculous statement, sir, and I think -- you ever to understand all the post-employment restrictions.
Most of the post-employment restrictions have to deal with representing the company before the agency, so I could not attend any meetings, could not speak to FDA employees, could not interact with anyone at FDA regarding this particular company for a period of actually two years --

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BY MR. SLATER:
Q. Do you still -- I'm sorry.
A. -- two years.
Q. Do you still talk to people at the FDA?
A. I do now after my post-employment restrictions have expired in terms of the two-year restriction.
Q. Do you still talk to people at the FDA who were involved in the Advanced Sterilization Products matter at any point?
A. No, I have not.
Q. Did you tell anyone at the FDA that you were working on behalf of Advanced Sterilization Products?
A. No, I have not.
MS. KABBASH: Objection.
BY MR. SLATER:
Q. Do you think that Congress perhaps might be a little concerned if they heard about this situation where you actually brought the enforcement action and then jumped to the other side and are now consulting for the company that you brought the action against?
A. Sir, they'd be concerned --

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MS. KABBASH: Objection.
THE WITNESS: -- about me complying with the post-employment restrictions, which they created and which I have complied with.
MR. SLATER: Maybe they'd be -- and maybe they'd be concerned that those restrictions aren't tight enough and maybe they need to be tightened up?
MS. KABBASH: Objection.
MR. SLATER: What do you think?
MS. KABBASH: Objection; argumentative, harassing.
THE WITNESS: I think they have better things to do, sir.
MR. SLATER: Well, I don't know that it's argumentative, harassing, and I'm sorry if I'm -- if you feel like I'm belaboring the point, but I think this is directly relevant to certain factors that a jury may consider about this witness in any trial he testifies in with regard to any device or product anywhere in the United States, including, but not limited to, for Johnson & Johnson and its affiliates.
BY MR. SLATER:
Q. Have you consulted for any -- for

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Johnson & Johnson or any of its other companies outside of a -- outside of the context of pelvic mesh or DePuy?
Other than this Advanced Sterilization Products matter, are there any others?
A. No.
Q. Have there been any others?
A. I don't think so.
Q. You saw no reason to doubt the qualifications or competence of the Ethicon Regulatory Affairs people that worked on the Prolift and Prolift+M projects; correct?
A. I had no reason to doubt their -- competence, I think you said -- that's correct.
Q. Yep.
For example, you saw how they defined regulatory terminology in their depositions and talked about what their obligations were. There was nothing you saw that you disagreed with. Right?
A. No, they seemed to understand the rules, regulations, policy, procedures.
MR. SLATER: I don't have any other questions.
MS. KABBASH: I just have a couple.

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EXAMINATION
- - -
BY MS. KABBASH:
Q. Mr. Utalowski, after you left the FDA, did you take seriously the obligations imposed on you with regard to post-FDA employment restrictions?
A. Absolutely.
Q. Did you make efforts to learn what those restrictions were?
A. Well, you're -- you're briefed on those restrictions on the final days of your employment at FDA.
And then I took the initiative to voluntarily interact with the Office of Integrity at FDA to further discuss and explore those restrictions in regard to consulting activities.
Q. And in your discussions with them, did you have all of your concerns or questions answered?
A. Yes, and there was no limitations imposed on what I had discussed with them about my consulting activities.
Q. Are you -- have you been committed

since you left the FDA to comply with those post-employment restrictions?
A. Yes, absolutely.
Q. And do you believe that you have?
MR. SLATER: Objection.
THE WITNESS: Yes, I do.
MR. SLATER: Objection.
BY MS. KABBASH:
Q. Is there any law or rule of ethics that you can point to that bars you from acting as a consultant for ASP now that you've left FDA?
A. None whatsoever.
MR. SLATER: Objection.
BY MS. KABBASH:
Q. Is there any law or rule that you are aware of that requires you to disclose at this time your consulting -- to FDA your consulting role with ASP?
A. No, none whatsoever.
MR. SLATER: Objection.
MS. KABBASH: That's all I have.
MR. DONELAN: No questions.
MR. SLATER: Thank you very much.
MS. KABBASH: Thank you.
THE VIDEO TECHNICIAN: Time now is

4:41. This deposition has concluded.
(Witness excused.)
(Deposition concluded at approximately 4:41 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

KIMBERLY A. CAHILL, a Federally Approved Registered Merit Reporter and Notary Public
Dated: August 20, 2013

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.
After doing so, please sign the errata sheet and date it.
You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.
It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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PAGE	LINE	CHANGE/REASON

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1-244, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

TIMOTHY A. ULATOWSKI DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

PAGE	LINE	